Dossier zur Nutzenbewertung gemäß § 35a SGB V

Tralokinumab (Adtralza®)

LEO Pharma GmbH

Separater Anhang 4-G zu Modul 4 A

Behandlung von mittelschwerer bis schwerer atopischer Dermatitis bei Erwachsenen, die für eine kontinuierliche systemische Therapie in Frage kommen.

Stand: 14.07.2021

CONFIDENTIAL

Tralokinumab

GBA

Payer submission statistical appendix

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Statistical appendix

Table 1.1.101.3.1.1: Total, Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	126	252
Age (years)		
Mean (sd)	37.8 (14.8)	39.7 (15.3)
Gender		
Female	43 (34.1%)	127 (50.4%)
Male	83 (65.9%)	125 (49.6%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	27.0 (5.6)	27.6 (6.7)
Race		
Asian	24 (19.0%)	17 (6.7%)
Black	12 (9.5%)	22 (8.7%)
White	84 (66.7%)	203 (80.6%)
Other	6 (4.8%)	10 (4.0%)
Geographic region		
Europe	72 (57.1%)	147 (58.3%)
USA	54 (42.9%)	105 (41.7%)
Body surface area (BSA) with AD (%)		
Mean (sd)	48.8 (25.9)	47.5 (23.3)
Duration of AD (years)		
Mean (sd)	28.7 (15.1)	27.9 (16.4)
Eczema Area and Severity Index (EASI)		
Mean (sd)	30.4 (12.8)	28.8 (12.0)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	66 (52.4%)	136 (54.0%)
Severe [IGA=4]	60 (47.6%)	116 (46.0%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.9 (1.5)	7.7 (1.5)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.1 (2.2)	6.9 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	68.9 (13.2)	67.0 (13.3)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	17.2 (7.2)	17.6 (7.1)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	11.8 (7.7)	11.7 (7.4)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	59.4 (23.1)	59.1 (25.0)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.589 (0.28)	0.561 (0.28)
Patients that have tried systemic corticosteroids (%)		
No	41 (32.5%)	105 (41.7%)
Yes	85 (67.5%)	147 (58.3%)
Previous number of treatments with systemic immunosuppressants*		
0	62 (49.2%)	159 (63.1%)
1	39 (31.0%)	64 (25.4%)
2	18 (14.3%)	19 (7.5%)
3	5 (4.0%)	5 (2.0%)
4	1 (0.8%)	4 (1.6%)
5	1 (0.8%)	1 (0.4%)

Table 1.1.101.3.1.1: Total, Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

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Table 1.1.101.4.1.1: Total, Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	137	138
Age (years)		
Mean (sd)	36.1 (13.7)	36.8 (14.6)
Gender		
Female	54 (39.4%)	57 (41.3%)
Male	83 (60.6%)	81 (58.7%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	25.8 (5.8)	25.1 (4.2)
Race		
Asian	1 (0.7%)	
Black	1 (0.7%)	
White	135 (98.5%)	135 (97.8%)
Other		3 (2.2%)
Geographic region		
Europe	137 (100%)	138 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	55.2 (22.9)	54.1 (21.8)
Duration of AD (years)		
Mean (sd)	25.3 (14.1)	27.1 (13.8)
Eczema Area and Severity Index (EASI)		
Mean (sd)	33.8 (13.5)	32.1 (11.5)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	70 (51.1%)	68 (49.3%)
Severe [IGA=4]	67 (48.9%)	70 (50.7%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.5 (1.4)	7.3 (1.5)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.9 (1.6)	6.3 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	70.8 (12.8)	70.2 (12.0)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	16.4 (6.3)	15.9 (6.5)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	11.8 (7.5)	10.7 (6.4)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	52.5 (22.0)	56.6 (19.9)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.591 (0.24)	0.634 (0.22)
Patients that have tried systemic corticosteroids (%)		
No	46 (33.6%)	41 (29.7%)
Yes	91 (66.4%)	97 (70.3%)
Previous number of treatments with systemic immunosuppressants*		
0	23 (16.8%)	22 (15.9%)
1	78 (56.9%)	85 (61.6%)
2	27 (19.7%)	22 (15.9%)
3	6 (4.4%)	8 (5.8%)
4	2 (1.5%)	1 (0.7%)
5	1 (0.7%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.1.102.3.1: Total, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Analysis set				
N	126		252	
Blood and lymphatic system disorders				
Anaemia			7	(2.8)
Lymphadenopathy	2	(1.6)		
Dermatopathic lymphadenopathy			1	(0.4)
Eosinophilia			1	(0.4)
Hypercoagulation			1	(0.4)
Hypereosinophilic syndrome			1	(0.4)
Iron deficiency anaemia			1	(0.4)
Leukocytosis			1	(0.4)
Lymphadenitis			1	(0.4)
Cardiac disorders				
Bundle branch block right	1	(0.8)	3	(1.2)
Atrial fibrillation			2	(0.8)
Atrioventricular block first degree	1	(0.8)		
Cardiac failure chronic			2	(0.8)
Ventricular extrasystoles	1	(0.8)		
Angina pectoris			1	(0.4)
Arrhythmia			1	(0.4)
Bradycardia			1	(0.4)
Bundle branch block left			1	(0.4)
Myocardial infarction			1	(0.4)
Congenital, familial and genetic disorders				
Atrial septal defect	2	(1.6)		
Gilbert's syndrome	2	(1.6)		
Ichthyosis	2	(1.6)	1	(0.4)
Congenital naevus	1	(0.8)		
Multiple lentigines syndrome	1	(0.8)		
Thalassaemia beta	1	(0.8)		
Type V hyperlipidaemia			2	(0.8)
Arrhythmogenic right ventricular dysplasia			1	(0.4)
Deafness congenital			1	(0.4)
Sickle cell trait			1	(0.4)
Tourette's disorder			1	(0.4)
Ear and labyrinth disorders				
Deafness			2	(0.8)
Deafness bilateral	1	(0.8)	2	(0.8)
Deafness unilateral	1	(0.8)		
Hyperacusis	1	(0.8)		
Vertigo			2	(0.8)
Vertigo positional	1	(0.8)		
Tinnitus			1	(0.4)
Endocrine disorders				
Hypothyroidism	4	(3.2)	11	(4.4)
Autoimmune thyroiditis			2	(0.8)
Basedow's disease			1	(0.4)
Hyperthyroidism			1	(0.4)
Thyroid mass			1	(0.4)
Eye disorders				
Conjunctivitis allergic	26	(20.6)	54	(21.4)
Atopic keratoconjunctivitis	4	(3.2)	7	(2.8)
Cataract	1	(0.8)	3	(1.2)
Dry eye			3	(1.2)
Myopia			3	(1.2)
Blepharitis	1	(0.8)	1	(0.4)
Blindness unilateral	1	(0.8)	1	(0.4)
Glaucoma			2	(0.8)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.1.102.3.1: Total, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Total				
Eye disorders				
Keratitis	1	(0.8)		
Keratoconus	1	(0.8)	1	(0.4)
Presbyopia			2	(0.8)
Visual impairment	1	(0.8)		
Allergic keratitis			1	(0.4)
Astigmatism			1	(0.4)
Blindness			1	(0.4)
Blindness day			1	(0.4)
Corneal opacity			1	(0.4)
Ectropion			1	(0.4)
Eczema eyelids			1	(0.4)
Eye pruritus			1	(0.4)
Eyelid oedema			1	(0.4)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	5	(4.0)	19	(7.5)
Dyspepsia	3	(2.4)	5	(2.0)
Gastritis	2	(1.6)	1	(0.4)
Constipation	1	(0.8)	3	(1.2)
Haemorrhoids			3	(1.2)
Irritable bowel syndrome	1	(0.8)	3	(1.2)
Cheilitis	1	(0.8)		
Chronic gastritis	1	(0.8)		
Colitis ulcerative	1	(0.8)	1	(0.4)
Diarrhoea	1	(0.8)		
Dysphagia	1	(0.8)		
Hiatus hernia	1	(0.8)		
Pancreatic cyst	1	(0.8)		
Abdominal distension			1	(0.4)
Crohn's disease			1	(0.4)
Diverticulum			1	(0.4)
Large intestine polyp			1	(0.4)
Nausea			1	(0.4)
Oesophagitis			1	(0.4)
Stress ulcer			1	(0.4)
Tooth malformation			1	(0.4)
General disorders and administration site conditions				
Drug intolerance			2	(0.8)
Fatigue	1	(0.8)		
Pain			2	(0.8)
Asthenia			1	(0.4)
Drug chemical incompatibility			1	(0.4)
Gait disturbance			1	(0.4)
Hernia			1	(0.4)
Peripheral swelling			1	(0.4)
Hepatobiliary disorders				
Hyperbilirubinaemia	1	(0.8)		
Cholelithiasis			1	(0.4)
Immune system disorders				
Seasonal allergy	56	(44.4)	121	(48.0)
Food allergy	44	(34.9)	83	(32.9)
Drug hypersensitivity	11	(8.7)	22	(8.7)
Hypersensitivity	7	(5.6)	17	(6.7)
Allergy to animal	6	(4.8)	13	(5.2)
Multiple allergies	3	(2.4)	13	(5.2)
Dust allergy			8	(3.2)
Mite allergy	4	(3.2)	5	(2.0)
Rubber sensitivity	4	(3.2)	5	(2.0)
Allergy to chemicals	1	(0.8)	4	(1.6)
Allergy to metals	2	(1.6)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.1.102.3.1: Total, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Immune system disorders				
Allergy to metals			3	(1.2)
Sensitisation	2	(1.6)		
Milk allergy	1	(0.8)	3	(1.2)
Allergy to arthropod sting			2	(0.8)
Allergy to plants			2	(0.8)
Perfume sensitivity	1	(0.8)		
Iodine allergy			1	(0.4)
Mycotic allergy			1	(0.4)
Reaction to colouring			1	(0.4)
Infections and infestations				
Herpes simplex	7	(5.6)	8	(3.2)
Oral herpes	3	(2.4)	6	(2.4)
Rhinitis	2	(1.6)	4	(1.6)
Chronic sinusitis	1	(0.8)	1	(0.4)
Conjunctivitis	1	(0.8)	2	(0.8)
Eczema herpeticum	1	(0.8)	1	(0.4)
Hordeolum	1	(0.8)		
Conjunctivitis bacterial			1	(0.4)
Folliculitis			1	(0.4)
Onychomycosis			1	(0.4)
Paronychia			1	(0.4)
Sinusitis			1	(0.4)
Tinea versicolour			1	(0.4)
Urinary tract infection			1	(0.4)
Viral upper respiratory tract infection			1	(0.4)
Injury, poisoning and procedural complications				
Joint injury			2	(0.8)
Ligament rupture	1	(0.8)		
Muscle strain	1	(0.8)		
Foot fracture			1	(0.4)
Ligament sprain			1	(0.4)
Limb injury			1	(0.4)
Meniscus injury			1	(0.4)
Tendon injury			1	(0.4)
Tendon rupture			1	(0.4)
Tibia fracture			1	(0.4)
Ulnar nerve injury			1	(0.4)
Investigations				
Blood cholesterol increased	3	(2.4)	2	(0.8)
Alanine aminotransferase increased	1	(0.8)	1	(0.4)
Basophil count decreased	1	(0.8)		
Blood bilirubin increased	1	(0.8)		
Blood immunoglobulin E increased	1	(0.8)	2	(0.8)
Blood lactate dehydrogenase increased	1	(0.8)		
Blood pressure increased	1	(0.8)		
Blood triglycerides increased	1	(0.8)		
Cardiac murmur	1	(0.8)		
Electrocardiogram QT shortened	1	(0.8)		
Gamma-glutamyltransferase increased	1	(0.8)	1	(0.4)
Low density lipoprotein increased	1	(0.8)	1	(0.4)
Mean cell volume decreased	1	(0.8)		
Eosinophil count increased			1	(0.4)
Hepatic enzyme increased			1	(0.4)
Human papilloma virus test			1	(0.4)
Human papilloma virus test positive			1	(0.4)
Vitamin D decreased			1	(0.4)
Metabolism and nutrition disorders				
Obesity	4	(3.2)	14	(5.6)
Hypercholesterolaemia	2	(1.6)	11	(4.4)
Type 2 diabetes mellitus	4	(3.2)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.1.102.3.1: Total, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Metabolism and nutrition disorders				
Type 2 diabetes mellitus			11	(4.4)
Hyperlipidaemia	2	(1.6)	9	(3.6)
Gout	3	(2.4)	4	(1.6)
Lactose intolerance	1	(0.8)	6	(2.4)
Hypertriglyceridaemia	1	(0.8)	5	(2.0)
Vitamin D deficiency	2	(1.6)	3	(1.2)
Gluten sensitivity			3	(1.2)
Decreased appetite	1	(0.8)	1	(0.4)
Diabetes mellitus	1	(0.8)	2	(0.8)
Dyslipidaemia	1	(0.8)		
Folate deficiency	1	(0.8)		
Haemochromatosis	1	(0.8)		
Hyperuricaemia			2	(0.8)
Cow's milk intolerance			1	(0.4)
Fructose intolerance			1	(0.4)
Glucose tolerance impaired			1	(0.4)
Hypoglycaemia			1	(0.4)
Hypokalaemia			1	(0.4)
Iodine deficiency			1	(0.4)
Overweight			1	(0.4)
Vitamin B12 deficiency			1	(0.4)
Musculoskeletal and connective tissue disorders				
Osteoarthritis	3	(2.4)	11	(4.4)
Back pain	2	(1.6)	10	(4.0)
Intervertebral disc protrusion			6	(2.4)
Arthralgia	2	(1.6)	5	(2.0)
Arthritis	1	(0.8)	3	(1.2)
Scoliosis			3	(1.2)
Ankylosing spondylitis	1	(0.8)	1	(0.4)
Fibromyalgia	1	(0.8)		
Intervertebral disc degeneration	1	(0.8)	1	(0.4)
Joint instability	1	(0.8)		
Muscle spasms			2	(0.8)
Neck pain	1	(0.8)	1	(0.4)
Pain in extremity	1	(0.8)		
Plantar fasciitis	1	(0.8)	1	(0.4)
Psoriatic arthropathy	1	(0.8)		
Rheumatoid arthritis			2	(0.8)
Rotator cuff syndrome	1	(0.8)		
Systemic lupus erythematosus	1	(0.8)		
Bursitis			1	(0.4)
Costochondritis			1	(0.4)
Haemarthrosis			1	(0.4)
Intervertebral disc disorder			1	(0.4)
Joint swelling			1	(0.4)
Limb asymmetry			1	(0.4)
Muscle tightness			1	(0.4)
Muscular weakness			1	(0.4)
Neuropathic arthropathy			1	(0.4)
Osteonecrosis			1	(0.4)
Osteoporosis			1	(0.4)
Temporomandibular joint syndrome			1	(0.4)
Vertebral osteophyte			1	(0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Seborrhoeic keratosis			3	(1.2)
Acoustic neuroma	1	(0.8)		
Haemangioma	1	(0.8)	1	(0.4)
Skin papilloma	1	(0.8)		
Leiomyoma			1	(0.4)
Lipoma			1	(0.4)
Uterine leiomyoma			1	(0.4)
Nervous system disorders				
Headache	3	(2.4)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.1.102.3.1: Total, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Total				
Nervous system disorders				
Headache			12	(4.8)
Migraine	4	(3.2)	7	(2.8)
Carpal tunnel syndrome			2	(0.8)
Cervical radiculopathy	1	(0.8)		
Diabetic neuropathy			2	(0.8)
Seizure	1	(0.8)	1	(0.4)
Tension headache	1	(0.8)		
Delayed sleep phase			1	(0.4)
Dizziness			1	(0.4)
Epilepsy			1	(0.4)
Lumbar radiculopathy			1	(0.4)
Migraine with aura			1	(0.4)
Somnolence			1	(0.4)
Psychiatric disorders				
Depression	3	(2.4)	24	(9.5)
Anxiety	5	(4.0)	15	(6.0)
Insomnia	3	(2.4)	12	(4.8)
Anxiety disorder	3	(2.4)		
Autism spectrum disorder	3	(2.4)		
Attention deficit/hyperactivity disorder	2	(1.6)	3	(1.2)
Body dysmorphic disorder	1	(0.8)		
Depersonalisation/derealisation disorder	1	(0.8)		
Generalised anxiety disorder	1	(0.8)		
Sleep disorder	1	(0.8)	1	(0.4)
Stress	1	(0.8)		
Bulimia nervosa			1	(0.4)
Oppositional defiant disorder			1	(0.4)
Post-traumatic stress disorder			1	(0.4)
Social anxiety disorder			1	(0.4)
Renal and urinary disorders				
Renal cyst	2	(1.6)	1	(0.4)
Chronic kidney disease	1	(0.8)	1	(0.4)
Pollakiuria	1	(0.8)		
Renal colic	1	(0.8)		
Automatic bladder			1	(0.4)
Haematuria			1	(0.4)
Renal failure			1	(0.4)
Reproductive system and breast disorders				
Benign prostatic hyperplasia			2	(0.8)
Cervical dysplasia	1	(0.8)		
Dysmenorrhoea			2	(0.8)
Erectile dysfunction	1	(0.8)	1	(0.4)
Pelvic congestion	1	(0.8)		
Ovarian cyst			1	(0.4)
Respiratory, thoracic and mediastinal disorders				
Asthma	58	(46.0)	119	(47.2)
Rhinitis allergic	15	(11.9)	23	(9.1)
Chronic obstructive pulmonary disease	4	(3.2)	7	(2.8)
Sleep apnoea syndrome	1	(0.8)	7	(2.8)
Nasal polyps	1	(0.8)		
Rhinitis perennial	1	(0.8)		
Adenoidal hypertrophy			1	(0.4)
Dyspnoea			1	(0.4)
Lung cyst			1	(0.4)
Vocal cord dysfunction			1	(0.4)
Skin and subcutaneous tissue disorders				
Vitiligo	4	(3.2)	3	(1.2)
Acne			6	(2.4)
Alopecia areata	3	(2.4)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.1.102.3.1: Total, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Skin and subcutaneous tissue disorders				
Alopecia areata			4	(1.6)
Androgenetic alopecia	3	(2.4)	3	(1.2)
Alopecia	2	(1.6)	3	(1.2)
Dermal cyst	2	(1.6)	1	(0.4)
Dermatitis contact	2	(1.6)	4	(1.6)
Pruritus	2	(1.6)	1	(0.4)
Actinic keratosis			2	(0.8)
Alopecia universalis	1	(0.8)		
Chronic spontaneous urticaria	1	(0.8)	1	(0.4)
Dermatitis papillaris capillitii	1	(0.8)		
Dyshidrotic eczema	1	(0.8)		
Hyperkeratosis	1	(0.8)		
Neurodermatitis	1	(0.8)	1	(0.4)
Psoriasis	1	(0.8)		
Transient acantholytic dermatosis	1	(0.8)		
Urticaria	1	(0.8)	2	(0.8)
Acanthosis nigricans			1	(0.4)
Dry skin			1	(0.4)
Hidradenitis			1	(0.4)
Keratosis pilaris			1	(0.4)
Lichen sclerosus			1	(0.4)
Rosacea			1	(0.4)
Social circumstances				
Tobacco user	5	(4.0)	5	(2.0)
Postmenopause	3	(2.4)	2	(0.8)
Menopause			1	(0.4)
Surgical and medical procedures				
Alcohol rehabilitation	1	(0.8)		
Appendicectomy	1	(0.8)		
Caesarean section	1	(0.8)		
Heart valve replacement	1	(0.8)	1	(0.4)
Immune tolerance induction	1	(0.8)		
Osteosynthesis	1	(0.8)		
Vasectomy	1	(0.8)		
Cataract operation			1	(0.4)
Continuous positive airway pressure			1	(0.4)
Corneal transplant			1	(0.4)
Hip arthroplasty			1	(0.4)
Intra-uterine contraceptive device			1	(0.4)
Intra-uterine contraceptive device insertion			1	(0.4)
Keratoplasty			1	(0.4)
Knee arthroplasty			1	(0.4)
Vascular disorders				
Hypertension	20	(15.9)	43	(17.1)
Peripheral vascular disorder			3	(1.2)
Lymphoedema	1	(0.8)		
Raynaud's phenomenon	1	(0.8)		
Arteriosclerosis			1	(0.4)
Deep vein thrombosis			1	(0.4)
Poor peripheral circulation			1	(0.4)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.1.102.4.1: Total, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Total				
Analysis set				
N	137		138	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	1	(0.7)		
Thrombocytopenia	1	(0.7)		
Eosinophilia			1	(0.7)
Iron deficiency anaemia			1	(0.7)
Lymphadenopathy			1	(0.7)
Lymphopenia			1	(0.7)
Cardiac disorders				
Bundle branch block right	3	(2.2)		
Atrial fibrillation	1	(0.7)	2	(1.4)
Sinus bradycardia	1	(0.7)	2	(1.4)
Atrial flutter	1	(0.7)		
Atrioventricular block	1	(0.7)		
Cardiomyopathy	1	(0.7)		
Myocardial infarction	1	(0.7)		
Myocardial ischaemia	1	(0.7)		
Atrioventricular block first degree			1	(0.7)
Bradycardia			1	(0.7)
Bundle branch block left			1	(0.7)
Congestive cardiomyopathy			1	(0.7)
Mitral valve incompetence			1	(0.7)
Tachycardia			1	(0.7)
Congenital, familial and genetic disorders				
Benign familial haematuria	1	(0.7)		
Congenital anomaly	1	(0.7)		
Congenital cystic kidney disease	1	(0.7)		
Cytogenetic abnormality	1	(0.7)		
Gilbert's syndrome	1	(0.7)		
Sickle cell anaemia	1	(0.7)		
Von Willebrand's disease			1	(0.7)
Ear and labyrinth disorders				
Deafness	1	(0.7)		
Deafness neurosensory	1	(0.7)		
Tinnitus	1	(0.7)		
Endocrine disorders				
Hypothyroidism	2	(1.5)	9	(6.5)
Autoimmune thyroiditis	3	(2.2)		
Thyroid mass	1	(0.7)		
Goitre			1	(0.7)
Hyperprolactinaemia			1	(0.7)
Thyroiditis			1	(0.7)
Eye disorders				
Conjunctivitis allergic	41	(29.9)	40	(29.0)
Atopic keratoconjunctivitis	9	(6.6)	1	(0.7)
Dry eye	3	(2.2)		
Keratoconus	3	(2.2)		
Cataract			3	(2.2)
Blepharitis			2	(1.4)
Myopia			2	(1.4)
Astigmatism	1	(0.7)		
Glaucoma	1	(0.7)	1	(0.7)
Keratitis			1	(0.7)
Photophobia			1	(0.7)
Retinal degeneration			1	(0.7)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	3	(2.2)		

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Table 1.1.102.4.1: Total, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Gastrointestinal disorders				
Gastrooesophageal reflux disease			4	(2.9)
Chronic gastritis	2	(1.5)	1	(0.7)
Hiatus hernia	2	(1.5)	1	(0.7)
Irritable bowel syndrome	2	(1.5)	1	(0.7)
Dyspepsia			2	(1.4)
Oesophagitis			2	(1.4)
Barrett's oesophagus	1	(0.7)	1	(0.7)
Coeliac disease	1	(0.7)	1	(0.7)
Crohn's disease	1	(0.7)		
Gastritis	1	(0.7)		
Haemorrhoids	1	(0.7)	1	(0.7)
Colitis ulcerative			1	(0.7)
Gastric ulcer			1	(0.7)
General disorders and administration site conditions				
Xerosis	1	(0.7)	4	(2.9)
Dysplasia	1	(0.7)		
Hernia	1	(0.7)		
Oedema peripheral	1	(0.7)		
Hepatobiliary disorders				
Hepatic steatosis			1	(0.7)
Immune system disorders				
Seasonal allergy	70	(51.1)	76	(55.1)
Food allergy	50	(36.5)	50	(36.2)
Allergy to animal	17	(12.4)	10	(7.2)
Mite allergy	16	(11.7)	14	(10.1)
Drug hypersensitivity	9	(6.6)	12	(8.7)
Multiple allergies	9	(6.6)	11	(8.0)
Allergy to metals	1	(0.7)	5	(3.6)
Hypersensitivity	4	(2.9)	3	(2.2)
Allergy to plants	3	(2.2)	4	(2.9)
Rubber sensitivity	1	(0.7)	4	(2.9)
Allergy to chemicals	1	(0.7)	3	(2.2)
Milk allergy	1	(0.7)	3	(2.2)
Dust allergy	1	(0.7)	2	(1.4)
Flour sensitivity	1	(0.7)		
Mycotic allergy	1	(0.7)	1	(0.7)
Iodine allergy			1	(0.7)
Oral allergy syndrome			1	(0.7)
Perfume sensitivity			1	(0.7)
Infections and infestations				
Herpes simplex	11	(8.0)	13	(9.4)
Sinusitis	2	(1.5)	1	(0.7)
Oral herpes	1	(0.7)	2	(1.4)
Rhinitis			2	(1.4)
Conjunctivitis	1	(0.7)		
Onychomycosis	1	(0.7)		
Ear infection			1	(0.7)
Epididymitis			1	(0.7)
Papilloma viral infection			1	(0.7)
Skin candida			1	(0.7)
Injury, poisoning and procedural complications				
Scar			2	(1.4)
Deafness traumatic	1	(0.7)		
Joint injury			1	(0.7)
Ligament sprain			1	(0.7)
Meniscus injury			1	(0.7)
Investigations				
Aspartate aminotransferase increased	1	(0.7)		

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Table 1.1.102.4.1: Total, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Investigations				
Blood immunoglobulin E increased	1	(0.7)	1	(0.7)
Gamma-glutamyltransferase increased	1	(0.7)	1	(0.7)
Lymph node palpable	1	(0.7)		
Mean cell volume increased	1	(0.7)		
Neutrophil count increased	1	(0.7)		
Vitamin B12 decreased	1	(0.7)		
White blood cell count increased	1	(0.7)		
Blood uric acid increased			1	(0.7)
Metabolism and nutrition disorders				
Hypercholesterolaemia	3	(2.2)	5	(3.6)
Diabetes mellitus			4	(2.9)
Dyslipidaemia	3	(2.2)	1	(0.7)
Gluten sensitivity	3	(2.2)		
Gout	3	(2.2)		
Lactose intolerance	3	(2.2)		
Hyperlipidaemia	2	(1.5)	1	(0.7)
Obesity	2	(1.5)	2	(1.4)
Vitamin D deficiency	2	(1.5)	2	(1.4)
Hyperuricaemia	1	(0.7)	2	(1.4)
Glucose tolerance impaired	1	(0.7)		
Iron deficiency	1	(0.7)	1	(0.7)
Mineral deficiency	1	(0.7)		
Type 2 diabetes mellitus	1	(0.7)		
Histamine intolerance			1	(0.7)
Hyperinsulinism			1	(0.7)
Hypertriglyceridaemia			1	(0.7)
Overweight			1	(0.7)
Purine metabolism disorder			1	(0.7)
Musculoskeletal and connective tissue disorders				
Back pain	1	(0.7)	5	(3.6)
Arthralgia	3	(2.2)		
Intervertebral disc protrusion	2	(1.5)	3	(2.2)
Osteoarthritis	2	(1.5)	3	(2.2)
Myalgia	2	(1.5)		
Osteopenia	2	(1.5)		
Osteoporosis	1	(0.7)	2	(1.4)
Growth retardation	1	(0.7)		
Intervertebral disc disorder	1	(0.7)		
Joint range of motion decreased	1	(0.7)		
Osteochondrosis	1	(0.7)		
Plica syndrome	1	(0.7)		
Spinal osteoarthritis	1	(0.7)		
Temporomandibular joint syndrome	1	(0.7)		
Ankylosing spondylitis			1	(0.7)
Fibromyalgia			1	(0.7)
Foot deformity			1	(0.7)
Lumbar spinal stenosis			1	(0.7)
Muscle spasms			1	(0.7)
Spinal pain			1	(0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Melanocytic naevus			4	(2.9)
Haemangioma	1	(0.7)		
Blepharal papilloma			1	(0.7)
Fibroma			1	(0.7)
Haemangioma of liver			1	(0.7)
Skin papilloma			1	(0.7)
Nervous system disorders				
Headache	5	(3.6)	7	(5.1)
Migraine	5	(3.6)		

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Table 1.1.102.4.1: Total, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Nervous system disorders				
Migraine			6	(4.3)
Restless legs syndrome	2	(1.5)		
Hypertonia			2	(1.4)
Dysaesthesia	1	(0.7)		
Epilepsy	1	(0.7)		
Hydrocephalus	1	(0.7)		
Migraine with aura	1	(0.7)		
Multiple sclerosis	1	(0.7)		
Narcolepsy	1	(0.7)		
Paralysis	1	(0.7)		
Psychiatric disorders				
Anxiety	1	(0.7)	5	(3.6)
Depression	4	(2.9)	3	(2.2)
Insomnia	2	(1.5)	1	(0.7)
Depressed mood	1	(0.7)	2	(1.4)
Eating disorder	1	(0.7)		
Fear of injection	1	(0.7)		
Nervousness	1	(0.7)		
Sleep disorder	1	(0.7)	1	(0.7)
Affective disorder			1	(0.7)
Attention deficit/hyperactivity disorder			1	(0.7)
Stress			1	(0.7)
Renal and urinary disorders				
Proteinuria	4	(2.9)		
Haematuria	2	(1.5)		
Nephrolithiasis			2	(1.4)
Incontinence	1	(0.7)		
Renal cyst	1	(0.7)		
Renal disorder	1	(0.7)		
Renal failure	1	(0.7)	1	(0.7)
Renal vein compression	1	(0.7)		
Chronic kidney disease			1	(0.7)
IgA nephropathy			1	(0.7)
Reproductive system and breast disorders				
Benign prostatic hyperplasia	2	(1.5)	1	(0.7)
Dysmenorrhoea	1	(0.7)	1	(0.7)
Erectile dysfunction	1	(0.7)		
Menstrual disorder	1	(0.7)		
Polycystic ovaries	1	(0.7)		
Premenstrual syndrome	1	(0.7)		
Gynaecomastia			1	(0.7)
Ovarian cyst			1	(0.7)
Testicular cyst			1	(0.7)
Respiratory, thoracic and mediastinal disorders				
Asthma	74	(54.0)	62	(44.9)
Rhinitis allergic	20	(14.6)	9	(6.5)
Nasal septum deviation	2	(1.5)	2	(1.4)
Chronic obstructive pulmonary disease			2	(1.4)
Bronchial hyperreactivity	1	(0.7)		
Nasal polyps	1	(0.7)		
Sinus disorder	1	(0.7)		
Bronchiectasis			1	(0.7)
Bronchitis chronic			1	(0.7)
Dysphonia			1	(0.7)
Nasal turbinate hypertrophy			1	(0.7)
Sleep apnoea syndrome			1	(0.7)
Skin and subcutaneous tissue disorders				
Alopecia areata	3	(2.2)	1	(0.7)
Alopecia	2	(1.5)		

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Table 1.1.102.4.1: Total, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Total				
Skin and subcutaneous tissue disorders				
Acne			2	(1.4)
Dermatitis contact	1	(0.7)	1	(0.7)
Photosensitivity reaction	1	(0.7)	1	(0.7)
Psoriasis	1	(0.7)		
Skin sensitisation	1	(0.7)		
Urticaria	1	(0.7)	1	(0.7)
Vitiligo	1	(0.7)	1	(0.7)
Androgenetic alopecia			1	(0.7)
Rosacea			1	(0.7)
Social circumstances				
Menopause			2	(1.4)
Postmenopause	1	(0.7)		
Surgical and medical procedures				
Female sterilisation	1	(0.7)		
Gastric bypass	1	(0.7)		
Lip lesion excision	1	(0.7)		
Maxillofacial operation	1	(0.7)		
Nasal septal operation	1	(0.7)		
Sterilisation	1	(0.7)		
Thyroid nodule removal	1	(0.7)		
Thyroidectomy	1	(0.7)		
Cardiac pacemaker insertion			1	(0.7)
Cardiac resynchronisation therapy			1	(0.7)
Contraception			1	(0.7)
Intra-uterine contraceptive device			1	(0.7)
Knee operation			1	(0.7)
Vascular disorders				
Hypertension	25	(18.2)	23	(16.7)
Peripheral venous disease	2	(1.5)	3	(2.2)
Varicose vein	1	(0.7)	1	(0.7)
Spider vein			1	(0.7)

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Table 1.1.103.3.1: Total, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Analysis set				
N	126		252	
Blood and lymphatic system disorders				
Dermatopathic lymphadenopathy	1	(0.8)		
Iron deficiency anaemia	1	(0.8)		
Cardiac disorders				
Myocardial infarction			3	(1.2)
Arrhythmia			1	(0.4)
Pericarditis			1	(0.4)
Wolff-Parkinson-White syndrome			1	(0.4)
Congenital, familial and genetic disorders				
Cryptorchism	1	(0.8)		
Phimosis	1	(0.8)		
Ventricular septal defect	1	(0.8)		
Ear and labyrinth disorders				
Ear disorder	1	(0.8)		
Eye disorders				
Conjunctivitis allergic	3	(2.4)	1	(0.4)
Atopic keratoconjunctivitis	2	(1.6)		
Cataract	2	(1.6)	4	(1.6)
Blepharitis	1	(0.8)	1	(0.4)
Keratoconus	1	(0.8)		
Myopia	1	(0.8)	1	(0.4)
Retinal detachment	1	(0.8)	1	(0.4)
Dry eye			1	(0.4)
Strabismus			1	(0.4)
Gastrointestinal disorders				
Haemorrhoids	2	(1.6)	2	(0.8)
Inguinal hernia	2	(1.6)	2	(0.8)
Chronic gastritis	1	(0.8)		
Abdominal adhesions			1	(0.4)
Abdominal hernia			1	(0.4)
Colitis			1	(0.4)
Gastrooesophageal reflux disease			1	(0.4)
Gingival recession			1	(0.4)
Lumbar hernia			1	(0.4)
Oesophagitis			1	(0.4)
Peptic ulcer			1	(0.4)
Rectal prolapse			1	(0.4)
Umbilical hernia			1	(0.4)
General disorders and administration site conditions				
Chest pain			1	(0.4)
Cyst			1	(0.4)
Fatigue			1	(0.4)
Inflammation			1	(0.4)
Hepatobiliary disorders				
Cholecystitis	1	(0.8)	2	(0.8)
Hepatic steatosis			1	(0.4)
Hepatitis			1	(0.4)
Immune system disorders				
Food allergy	3	(2.4)	3	(1.2)
Seasonal allergy			4	(1.6)
Allergy to animal			2	(0.8)
Drug hypersensitivity			1	(0.4)
Infections and infestations				
Eczema herpeticum	6	(4.8)		

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Table 1.1.103.3.1: Total, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Infections and infestations				
Eczema herpeticum			4	(1.6)
Impetigo	4	(3.2)	7	(2.8)
Appendicitis	1	(0.8)	4	(1.6)
Erysipelas	2	(1.6)		
Herpes simplex	2	(1.6)	3	(1.2)
Herpes zoster	2	(1.6)	3	(1.2)
Oral herpes	2	(1.6)	2	(0.8)
Staphylococcal skin infection	2	(1.6)		
Conjunctivitis			3	(1.2)
Sinusitis			3	(1.2)
Tonsillitis			3	(1.2)
Bronchitis	1	(0.8)	1	(0.4)
Cellulitis	1	(0.8)	2	(0.8)
Chronic sinusitis	1	(0.8)		
Fungal infection	1	(0.8)		
Furuncle			2	(0.8)
Gastrointestinal candidiasis	1	(0.8)		
Herpes virus infection	1	(0.8)		
Measles	1	(0.8)		
Molluscum contagiosum	1	(0.8)		
Osteomyelitis	1	(0.8)		
Peritonsillitis	1	(0.8)		
Poliomyelitis	1	(0.8)		
Staphylococcal infection	1	(0.8)	2	(0.8)
Varicella	1	(0.8)		
Abscess limb			1	(0.4)
Acarodermatitis			1	(0.4)
Acne pustular			1	(0.4)
Acute sinusitis			1	(0.4)
Adenoiditis			1	(0.4)
Ascariasis			1	(0.4)
Body tinea			1	(0.4)
Chronic tonsillitis			1	(0.4)
Clostridium difficile colitis			1	(0.4)
Conjunctivitis bacterial			1	(0.4)
Croup infectious			1	(0.4)
Dermatitis infected			1	(0.4)
External ear cellulitis			1	(0.4)
Keratitis viral			1	(0.4)
Kidney infection			1	(0.4)
Lyme disease			1	(0.4)
Neuroborreliosis			1	(0.4)
Oesophageal candidiasis			1	(0.4)
Otitis media			1	(0.4)
Papilloma viral infection			1	(0.4)
Pilonidal cyst			1	(0.4)
Pneumonia			1	(0.4)
Tinea cruris			1	(0.4)
Tinea pedis			1	(0.4)
Urinary tract infection bacterial			1	(0.4)
Viral upper respiratory tract infection			1	(0.4)
Vulvovaginal mycotic infection			1	(0.4)
Wound infection staphylococcal			1	(0.4)
Injury, poisoning and procedural complications				
Foot fracture	2	(1.6)	1	(0.4)
Wrist fracture	2	(1.6)		
Cartilage injury	1	(0.8)		
Clavicle fracture	1	(0.8)	1	(0.4)
Fall	1	(0.8)		
Hand fracture	1	(0.8)		
Ligament rupture	1	(0.8)	2	(0.8)
Radius fracture	1	(0.8)		
Upper limb fracture			2	(0.8)

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Table 1.1.103.3.1: Total, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Total		
Injury, poisoning and procedural complications		
Arthropod bite		1 (0.4)
Concussion		1 (0.4)
Femoral neck fracture		1 (0.4)
Injury		1 (0.4)
Jaw fracture		1 (0.4)
Meniscus injury		1 (0.4)
Investigations		
Arthroscopy	2 (1.6)	1 (0.4)
Blood pressure increased	1 (0.8)	
Colonoscopy	1 (0.8)	2 (0.8)
Endoscopy upper gastrointestinal tract	1 (0.8)	
Blood creatinine increased		1 (0.4)
Catheterisation cardiac		1 (0.4)
Endoscopy		1 (0.4)
Hysteroscopy		1 (0.4)
Laparoscopy		1 (0.4)
Smear cervix		1 (0.4)
Metabolism and nutrition disorders		
Hypercholesterolaemia	1 (0.8)	1 (0.4)
Protein deficiency	1 (0.8)	
Type 2 diabetes mellitus		1 (0.4)
Musculoskeletal and connective tissue disorders		
Arthralgia	1 (0.8)	1 (0.4)
Intervertebral disc protrusion	1 (0.8)	1 (0.4)
Juvenile idiopathic arthritis	1 (0.8)	
Limb mass	1 (0.8)	
Rotator cuff syndrome	1 (0.8)	
Back pain		1 (0.4)
Exostosis		1 (0.4)
Osteochondrosis		1 (0.4)
Pain in extremity		1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Haemangioma	2 (1.6)	
Acanthoma	1 (0.8)	
Basal cell carcinoma	1 (0.8)	1 (0.4)
Cervix carcinoma	1 (0.8)	
Meningioma	1 (0.8)	
Anogenital warts		1 (0.4)
Colon cancer		1 (0.4)
Dysplastic naevus		1 (0.4)
Lip squamous cell carcinoma		1 (0.4)
Osteochondroma		1 (0.4)
Skin papilloma		1 (0.4)
Nervous system disorders		
Cerebrovascular accident	2 (1.6)	1 (0.4)
Hydrocephalus	1 (0.8)	
Migraine		2 (0.8)
Trigeminal neuralgia	1 (0.8)	
Alcoholic seizure		1 (0.4)
Facial paresis		1 (0.4)
Headache		1 (0.4)
Sciatica		1 (0.4)
Pregnancy, puerperium and perinatal conditions		
Abortion		1 (0.4)
Abortion spontaneous		1 (0.4)
Ectopic pregnancy		1 (0.4)
Gestational hypertension		1 (0.4)

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Table 1.1.103.3.1: Total, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Psychiatric disorders				
Depression	3	(2.4)	5	(2.0)
Alcohol problem			1	(0.4)
Anxiety			1	(0.4)
Depressed mood			1	(0.4)
Drug use disorder			1	(0.4)
Renal and urinary disorders				
Nephrolithiasis			2	(0.8)
Glomerulonephritis			1	(0.4)
Reproductive system and breast disorders				
Menorrhagia	1	(0.8)		
Testicular retraction	1	(0.8)		
Cervical dysplasia			1	(0.4)
Dysmenorrhoea			1	(0.4)
Ovarian cyst			1	(0.4)
Ovarian cyst ruptured			1	(0.4)
Uterine polyp			1	(0.4)
Respiratory, thoracic and mediastinal disorders				
Asthma	6	(4.8)	14	(5.6)
Nasal septum deviation	2	(1.6)		
Nasal inflammation	1	(0.8)		
Nasal polyps	1	(0.8)		
Dyspnoea			1	(0.4)
Sleep apnoea syndrome			1	(0.4)
Skin and subcutaneous tissue disorders				
Urticaria	2	(1.6)	2	(0.8)
Acne	1	(0.8)	1	(0.4)
Dyshidrotic eczema			2	(0.8)
Neurodermatitis	1	(0.8)		
Dermatitis contact			1	(0.4)
Eczema			1	(0.4)
Hypersensitivity vasculitis			1	(0.4)
Papulopustular rosacea			1	(0.4)
Psoriasis			1	(0.4)
Rosacea			1	(0.4)
Social circumstances				
Infant			1	(0.4)
Postmenopause			1	(0.4)
Surgical and medical procedures				
Appendicectomy	5	(4.0)	13	(5.2)
Tonsillectomy	4	(3.2)	12	(4.8)
Caesarean section	1	(0.8)	10	(4.0)
Cholecystectomy	1	(0.8)	8	(3.2)
Hysterectomy	4	(3.2)	7	(2.8)
Eye operation	3	(2.4)		
Female sterilisation	3	(2.4)	4	(1.6)
Haemorrhoid operation	3	(2.4)	1	(0.4)
Knee operation	3	(2.4)	3	(1.2)
Wisdom teeth removal	3	(2.4)	2	(0.8)
Cataract operation	1	(0.8)	4	(1.6)
Corneal transplant	2	(1.6)		
Nasal septal operation	2	(1.6)	1	(0.4)
Skin neoplasm excision	2	(1.6)	1	(0.4)
Cardiac ablation			3	(1.2)
Foot operation			3	(1.2)
Inguinal hernia repair			3	(1.2)
Renal stone removal			3	(1.2)
Salpingectomy			3	(1.2)

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Table 1.1.103.3.1: Total, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Total		
Surgical and medical procedures		
Strabismus correction		3 (1.2)
Vasectomy	1 (0.8)	3 (1.2)
Adenoidectomy		2 (0.8)
Aortic bypass		2 (0.8)
Arthrodesis	1 (0.8)	
Carpal tunnel decompression		2 (0.8)
Circumcision	1 (0.8)	1 (0.4)
Craniotomy	1 (0.8)	
Cyst removal	1 (0.8)	
Endodontic procedure	1 (0.8)	1 (0.4)
Endometrial ablation	1 (0.8)	2 (0.8)
Explorative laparotomy		2 (0.8)
Gastric bypass	1 (0.8)	1 (0.4)
Heart valve replacement	1 (0.8)	
Hernia repair		2 (0.8)
Intraocular lens implant		2 (0.8)
Keratoplasty	1 (0.8)	
Laser therapy	1 (0.8)	
Ligament operation	1 (0.8)	2 (0.8)
Limb operation		2 (0.8)
Mammoplasty	1 (0.8)	
Metabolic surgery	1 (0.8)	
Muscle operation	1 (0.8)	
Nasal operation	1 (0.8)	2 (0.8)
Nasal polypectomy		2 (0.8)
Open reduction of fracture	1 (0.8)	
Plastic surgery	1 (0.8)	
Salpingo-oophorectomy	1 (0.8)	
Spinal decompression	1 (0.8)	
Spinal fusion surgery	1 (0.8)	1 (0.4)
Spinal operation		2 (0.8)
Steroid therapy	1 (0.8)	
Toe operation		2 (0.8)
Transfusion	1 (0.8)	
Turbinoplasty	1 (0.8)	
Uterine dilation and curettage	1 (0.8)	1 (0.4)
Abdominal hernia repair		1 (0.4)
Adenotonsillectomy		1 (0.4)
Angioplasty		1 (0.4)
Ankle arthroplasty		1 (0.4)
Ankle operation		1 (0.4)
Balneotherapy		1 (0.4)
Bone lesion excision		1 (0.4)
Bone operation		1 (0.4)
Brain lobectomy		1 (0.4)
Cardiac resynchronisation therapy		1 (0.4)
Carotid artery bypass		1 (0.4)
Colectomy		1 (0.4)
Eye laser surgery		1 (0.4)
Eyelid operation		1 (0.4)
Fracture treatment		1 (0.4)
Gingival graft		1 (0.4)
Hepatitis B immunisation		1 (0.4)
Hepatitis immunisation		1 (0.4)
Hernia hiatus repair		1 (0.4)
Immunisation		1 (0.4)
Implantable defibrillator insertion		1 (0.4)
In vitro fertilisation		1 (0.4)
Incisional drainage		1 (0.4)
Intervertebral disc operation		1 (0.4)
Keratomileusis		1 (0.4)
Lithotripsy		1 (0.4)
Meniscus operation		1 (0.4)

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Table 1.1.103.3.1: Total, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Total		
Surgical and medical procedures		
Myomectomy		1 (0.4)
Myopia correction		1 (0.4)
Oesophagogastric fundoplasty		1 (0.4)
Oophorectomy		1 (0.4)
Oral surgery		1 (0.4)
Osteosynthesis		1 (0.4)
Otoplasty		1 (0.4)
Ovarian cystectomy		1 (0.4)
Papilloma excision		1 (0.4)
Peritoneal adhesions division		1 (0.4)
Phototherapy		1 (0.4)
Rectal prolapse repair		1 (0.4)
Rhinoplasty		1 (0.4)
Sinus operation		1 (0.4)
Skin graft		1 (0.4)
Spinal laminectomy		1 (0.4)
Splenectomy		1 (0.4)
Stent placement		1 (0.4)
Tenoplasty		1 (0.4)
Umbilical hernia repair		1 (0.4)
Uvulectomy		1 (0.4)
Vascular disorders		
Kawasaki's disease	1 (0.8)	
Hypertension		1 (0.4)

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Table 1.1.103.4.1: Total, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Total				
Analysis set				
N	137		138	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	2	(1.5)		
Iron deficiency anaemia	1	(0.7)		
Neutropenia	1	(0.7)		
Cardiac disorders				
Bundle branch block left	1	(0.7)		
Cardiac failure	1	(0.7)		
Myocardial ischaemia			1	(0.7)
Pericarditis			1	(0.7)
Congenital, familial and genetic disorders				
Phimosis			2	(1.4)
Endocrine disorders				
Basedow's disease	1	(0.7)		
Goitre	1	(0.7)		
Thyroid mass			1	(0.7)
Eye disorders				
Conjunctivitis allergic	4	(2.9)	3	(2.2)
Cataract	1	(0.7)	3	(2.2)
Corneal oedema	1	(0.7)		
Keratitis	1	(0.7)	1	(0.7)
Lacrimation increased	1	(0.7)		
Atopic keratoconjunctivitis			1	(0.7)
Keratoconus			1	(0.7)
Retinal detachment			1	(0.7)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	1	(0.7)		
Pancreatitis acute	1	(0.7)		
Haemorrhoids			1	(0.7)
Hiatus hernia			1	(0.7)
Inguinal hernia			1	(0.7)
Intestinal obstruction			1	(0.7)
Proctitis			1	(0.7)
General disorders and administration site conditions				
Dysplasia	1	(0.7)		
Hernia			1	(0.7)
Hypothermia			1	(0.7)
Immune system disorders				
Seasonal allergy			2	(1.4)
Corneal graft rejection	1	(0.7)		
Hypersensitivity	1	(0.7)		
Oral allergy syndrome	1	(0.7)		
Mite allergy			1	(0.7)
Infections and infestations				
Impetigo	10	(7.3)	5	(3.6)
Herpes simplex	3	(2.2)	7	(5.1)
Eczema herpeticum	6	(4.4)	2	(1.4)
Herpes zoster	6	(4.4)	6	(4.3)
Appendicitis	2	(1.5)		
Infectious mononucleosis	2	(1.5)		
Meningitis	2	(1.5)		
Ophthalmic herpes simplex	2	(1.5)		
Oral herpes	2	(1.5)		
Varicella	2	(1.5)		

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Table 1.1.103.4.1: Total, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Total		
Infections and infestations		
Varicella		2 (1.4)
Erysipelas		2 (1.4)
Meningitis viral		2 (1.4)
Conjunctivitis	1 (0.7)	1 (0.7)
Dermatitis infected	1 (0.7)	
Enterobiasis	1 (0.7)	
Epiglottitis	1 (0.7)	
Furuncle	1 (0.7)	
Helicobacter gastritis	1 (0.7)	
Mumps	1 (0.7)	
Otitis externa	1 (0.7)	
Pilonidal cyst	1 (0.7)	
Pneumonia	1 (0.7)	
Postoperative wound infection	1 (0.7)	
Pyelonephritis	1 (0.7)	
Rhinitis	1 (0.7)	
Skin bacterial infection	1 (0.7)	
Staphylococcal infection	1 (0.7)	
Tinea cruris	1 (0.7)	
Tuberculosis	1 (0.7)	
Upper respiratory tract infection	1 (0.7)	
Urinary tract infection	1 (0.7)	
Bacterial infection		1 (0.7)
Cellulitis		1 (0.7)
Groin abscess		1 (0.7)
Herpes ophthalmic		1 (0.7)
Infection parasitic		1 (0.7)
Myringitis		1 (0.7)
Otitis media		1 (0.7)
Post procedural infection		1 (0.7)
Staphylococcal skin infection		1 (0.7)
Vaginal infection		1 (0.7)
Vulvovaginal candidiasis		1 (0.7)
Injury, poisoning and procedural complications		
Joint injury	2 (1.5)	
Upper limb fracture	2 (1.5)	2 (1.4)
Chillblains	1 (0.7)	
Clavicle fracture	1 (0.7)	
Facial bones fracture	1 (0.7)	1 (0.7)
Femur fracture	1 (0.7)	
Hand fracture	1 (0.7)	
Humerus fracture	1 (0.7)	
Joint dislocation	1 (0.7)	
Ligament injury	1 (0.7)	
Ligament rupture	1 (0.7)	
Meniscus injury	1 (0.7)	
Multiple fractures	1 (0.7)	
Wound secretion	1 (0.7)	
Ankle fracture		1 (0.7)
Comminuted fracture		1 (0.7)
Foot fracture		1 (0.7)
Ligament sprain		1 (0.7)
Limb fracture		1 (0.7)
Post-traumatic neck syndrome		1 (0.7)
Spinal fracture		1 (0.7)
Tibia fracture		1 (0.7)
Wrist fracture		1 (0.7)
Investigations		
Arthroscopy	1 (0.7)	
Biopsy breast	1 (0.7)	
Biopsy lymph gland	1 (0.7)	
Skin test	1 (0.7)	

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Table 1.1.103.4.1: Total, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Total		
Metabolism and nutrition disorders		
Hypoproteinaemia	1 (0.7)	
Starvation	1 (0.7)	
Lactose intolerance		1 (0.7)
Musculoskeletal and connective tissue disorders		
Bursitis	1 (0.7)	
Intervertebral disc protrusion	1 (0.7)	
Osteoarthritis	1 (0.7)	
Osteochondrosis	1 (0.7)	
Foot deformity		1 (0.7)
Joint contracture		1 (0.7)
Lumbar spinal stenosis		1 (0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Anogenital warts	2 (1.5)	
Acanthoma	1 (0.7)	
Basal cell carcinoma	1 (0.7)	
Benign pancreatic neoplasm	1 (0.7)	
Bowen's disease	1 (0.7)	
Breast cancer	1 (0.7)	
Melanocytic naevus	1 (0.7)	
Papilloma	1 (0.7)	
Prostate cancer	1 (0.7)	
Skin papilloma	1 (0.7)	
Squamous cell carcinoma of skin	1 (0.7)	
Bladder transitional cell carcinoma		1 (0.7)
Hodgkin's disease		1 (0.7)
Renal cancer		1 (0.7)
Sweat gland tumour		1 (0.7)
Testis cancer		1 (0.7)
Nervous system disorders		
Epilepsy	2 (1.5)	
Migraine	1 (0.7)	1 (0.7)
Restless legs syndrome	1 (0.7)	
Cerebral ischaemia		1 (0.7)
Paraesthesia		1 (0.7)
Seizure		1 (0.7)
Pregnancy, puerperium and perinatal conditions		
Abortion spontaneous	1 (0.7)	
HELLP syndrome	1 (0.7)	
Psychiatric disorders		
Depression	2 (1.5)	5 (3.6)
Alcoholism	1 (0.7)	
Drug use disorder	1 (0.7)	
Insomnia	1 (0.7)	
Mood altered	1 (0.7)	
Stress	1 (0.7)	
Adjustment disorder with depressed mood		1 (0.7)
Anxiety		1 (0.7)
Panic attack		1 (0.7)
Renal and urinary disorders		
Nephrolithiasis	2 (1.5)	
Acute kidney injury	1 (0.7)	
Hydronephrosis	1 (0.7)	
Renal colic		1 (0.7)
Ureterolithiasis		1 (0.7)
Reproductive system and breast disorders		
Acquired phimosis	1 (0.7)	

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Table 1.1.103.4.1: Total, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Total		
Reproductive system and breast disorders		
Breast cyst	1 (0.7)	
Polycystic ovaries	1 (0.7)	
Ovarian cyst		1 (0.7)
Sexual dysfunction		1 (0.7)
Varicocele		1 (0.7)
Respiratory, thoracic and mediastinal disorders		
Asthma	2 (1.5)	8 (5.8)
Rhinitis allergic	2 (1.5)	1 (0.7)
Maxillary sinus pseudocyst	1 (0.7)	
Bronchospasm		1 (0.7)
Pneumothorax		1 (0.7)
Pulmonary embolism		1 (0.7)
Skin and subcutaneous tissue disorders		
Dermatitis contact	2 (1.5)	1 (0.7)
Alopecia		2 (1.4)
Acne	1 (0.7)	1 (0.7)
Acne conglobata	1 (0.7)	
Dermal cyst	1 (0.7)	
Dermatitis exfoliative	1 (0.7)	
Rosacea	1 (0.7)	
Alopecia areata		1 (0.7)
Angioedema		1 (0.7)
Hidradenitis		1 (0.7)
Ingrowing nail		1 (0.7)
Purpura		1 (0.7)
Seborrhoeic dermatitis		1 (0.7)
Surgical and medical procedures		
Tonsillectomy	1 (0.7)	9 (6.5)
Appendicectomy	4 (2.9)	3 (2.2)
Adenoidectomy	3 (2.2)	2 (1.4)
Caesarean section	3 (2.2)	3 (2.2)
Cholecystectomy	3 (2.2)	1 (0.7)
Ligament operation	3 (2.2)	2 (1.4)
Cataract operation		3 (2.2)
Hysterectomy	2 (1.5)	3 (2.2)
Immunisation	2 (1.5)	
Nasal septal operation	2 (1.5)	1 (0.7)
Abscess drainage		2 (1.4)
Arthrodesis		2 (1.4)
Cyst removal	1 (0.7)	2 (1.4)
Knee operation		2 (1.4)
Nephrectomy		2 (1.4)
Turbinoplasty	1 (0.7)	2 (1.4)
UV light therapy		2 (1.4)
Benign tumour excision	1 (0.7)	
Cardiac ablation	1 (0.7)	
Carpal tunnel decompression	1 (0.7)	1 (0.7)
Endometrial ablation	1 (0.7)	
Eye laser surgery	1 (0.7)	
Finger amputation	1 (0.7)	
Hernia repair	1 (0.7)	
In vitro fertilisation	1 (0.7)	
Inguinal hernia repair	1 (0.7)	1 (0.7)
Jaw operation	1 (0.7)	
Keratoplasty	1 (0.7)	
Large intestinal polypectomy	1 (0.7)	
Meniscus operation	1 (0.7)	1 (0.7)
Myringotomy	1 (0.7)	
Oral surgery	1 (0.7)	
Ovarian cystectomy	1 (0.7)	

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Table 1.1.103.4.1: Total, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Total		
Surgical and medical procedures		
Pneumococcal immunisation	1 (0.7)	
Polypectomy	1 (0.7)	
Prophylaxis	1 (0.7)	
Shoulder operation	1 (0.7)	
Sinus operation	1 (0.7)	
Small intestinal resection	1 (0.7)	
Spinal operation	1 (0.7)	
Stent placement	1 (0.7)	
Strabismus correction	1 (0.7)	
Tooth extraction	1 (0.7)	1 (0.7)
Tumour excision	1 (0.7)	
Varicose vein operation	1 (0.7)	
Ventriculo-peritoneal shunt	1 (0.7)	
Wisdom teeth removal	1 (0.7)	1 (0.7)
Adrenalectomy		1 (0.7)
Amygdalotomy		1 (0.7)
Bunion operation		1 (0.7)
Cervical conisation		1 (0.7)
Circumcision		1 (0.7)
Eye operation		1 (0.7)
Female genital operation		1 (0.7)
Female sterilisation		1 (0.7)
Fracture treatment		1 (0.7)
Hepatitis B immunisation		1 (0.7)
Hospitalisation		1 (0.7)
Lip lesion excision		1 (0.7)
Meniscus removal		1 (0.7)
Myopia correction		1 (0.7)
Nasal polypectomy		1 (0.7)
Oophorectomy		1 (0.7)
Pleurodesis		1 (0.7)
Skin neoplasm excision		1 (0.7)
Thyroidectomy		1 (0.7)
Vascular disorders		
Hypertension	1 (0.7)	
Thrombophlebitis	1 (0.7)	1 (0.7)
Infarction		1 (0.7)

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Table 1.1.104.3.1: Total, Atopy history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	252 (100.0)	126 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	58 (23.0)	26 (20.6)
1-3	21 (8.3)	6 (4.8)
More than 3	37 (14.7)	20 (15.9)
Never	148 (58.7)	82 (65.1)
Past	34 (13.5)	11 (8.7)
1-3	21 (8.3)	6 (4.8)
More than 3	13 (5.2)	5 (4.0)
Unknown	12 (4.8)	7 (5.6)
ASTHMA		
Current	119 (47.2)	58 (46.0)
Never	104 (41.3)	50 (39.7)
Past	28 (11.1)	18 (14.3)
Unknown	1 (0.4)	
ATOPIC KERATOCONJUNCTIVITIS		
Current	8 (3.2)	5 (4.0)
1-3	6 (2.4)	1 (0.8)
More than 3	2 (0.8)	4 (3.2)
Never	228 (90.5)	110 (87.3)
Past	2 (0.8)	4 (3.2)
1-3	2 (0.8)	3 (2.4)
More than 3		1 (0.8)
Unknown	14 (5.6)	7 (5.6)
ECZEMA HERPETICUM		
Current	1 (0.4)	1 (0.8)
1-3	1 (0.4)	
More than 3		1 (0.8)
Never	218 (86.5)	112 (88.9)
Past	23 (9.1)	9 (7.1)
1-3	18 (7.1)	8 (6.3)
More than 3	5 (2.0)	1 (0.8)
Unknown	10 (4.0)	4 (3.2)
FOOD ALLERGY		
Current	89 (35.3)	48 (38.1)
Never	145 (57.5)	69 (54.8)
Past	9 (3.6)	3 (2.4)
Unknown	9 (3.6)	6 (4.8)
HAY FEVER		
Current	141 (56.0)	68 (54.0)
Never	88 (34.9)	51 (40.5)
Past	17 (6.7)	3 (2.4)
Unknown	6 (2.4)	4 (3.2)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.1.104.4.1: Total, Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	138 (100.0)	137 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	41 (29.7)	41 (29.9)
More than 3	24 (17.4)	29 (21.2)
Never	72 (52.2)	74 (54.0)
Past	22 (15.9)	21 (15.3)
More than 3	12 (8.7)	12 (8.8)
Unknown	3 (2.2)	1 (0.7)
ASTHMA		
Current	62 (44.9)	74 (54.0)
Never	63 (45.7)	58 (42.3)
Past	13 (9.4)	5 (3.6)
ATOPIC KERATOCONJUNCTIVITIS		
Current		9 (6.6)
More than 3		5 (3.6)
Never	131 (94.9)	117 (85.4)
Past	4 (2.9)	9 (6.6)
More than 3		3 (2.2)
Unknown	3 (2.2)	2 (1.5)
ECZEMA HERPETICUM		
Never	121 (87.7)	118 (86.1)
Past	14 (10.1)	15 (10.9)
More than 3	4 (2.9)	3 (2.2)
Unknown	3 (2.2)	4 (2.9)
FOOD ALLERGY		
Current	56 (40.6)	55 (40.1)
Never	78 (56.5)	77 (56.2)
Past	2 (1.4)	2 (1.5)
Unknown	2 (1.4)	3 (2.2)
HAY FEVER		
Current	76 (55.1)	77 (56.2)
Never	51 (37.0)	52 (38.0)
Past	10 (7.2)	5 (3.6)
Unknown	1 (0.7)	3 (2.2)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.1.105.3.1: Total, Skin disease history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	252 (100.0)	126 (100.0)
ALOPECIA		
Current	10 (4.0)	8 (6.3)
Never	237 (94.0)	115 (91.3)
Past	4 (1.6)	1 (0.8)
Unknown	1 (0.4)	2 (1.6)
CELLULITIS		
Never	235 (93.3)	118 (93.7)
Past	12 (4.8)	6 (4.8)
1-3	11 (4.4)	5 (4.0)
More than 3	1 (0.4)	1 (0.8)
Unknown	5 (2.0)	2 (1.6)
HERPES SIMPLEX		
Current	11 (4.4)	8 (6.3)
1-3	5 (2.0)	2 (1.6)
More than 3	6 (2.4)	6 (4.8)
Never	185 (73.4)	99 (78.6)
Past	51 (20.2)	17 (13.5)
1-3	32 (12.7)	12 (9.5)
More than 3	19 (7.5)	5 (4.0)
Unknown	5 (2.0)	2 (1.6)
IMPETIGO		
Never	201 (79.8)	107 (84.9)
Past	38 (15.1)	13 (10.3)
1-3	28 (11.1)	9 (7.1)
More than 3	10 (4.0)	4 (3.2)
Unknown	13 (5.2)	6 (4.8)
OTHER SKIN INFECTIONS		
Never	216 (85.7)	103 (81.7)
Past	27 (10.7)	14 (11.1)
Unknown	9 (3.6)	9 (7.1)
VITILIGO		
Current	3 (1.2)	4 (3.2)
Never	247 (98.0)	122 (96.8)
Past	1 (0.4)	
Unknown	1 (0.4)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.1.105.4.1: Total, Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	138 (100.0)	137 (100.0)
ALOPECIA		
Current	2 (1.4)	5 (3.6)
Never	133 (96.4)	130 (94.9)
Past	2 (1.4)	1 (0.7)
Unknown	1 (0.7)	1 (0.7)
CELLULITIS		
Never	130 (94.2)	130 (94.9)
Past	3 (2.2)	7 (5.1)
Unknown	5 (3.6)	
HERPES SIMPLEX		
Current	14 (10.1)	12 (8.8)
More than 3	7 (5.1)	8 (5.8)
Never	92 (66.7)	89 (65.0)
Past	28 (20.3)	35 (25.5)
More than 3	12 (8.7)	23 (16.8)
Unknown	4 (2.9)	1 (0.7)
IMPETIGO		
Never	108 (78.3)	99 (72.3)
Past	27 (19.6)	36 (26.3)
More than 3	8 (5.8)	13 (9.5)
Unknown	3 (2.2)	2 (1.5)
OTHER SKIN INFECTIONS		
Never	117 (84.8)	117 (85.4)
Past	12 (8.7)	15 (10.9)
Unknown	9 (6.5)	5 (3.6)
VITILIGO		
Current	1 (0.7)	1 (0.7)
Never	135 (97.8)	136 (99.3)
Past	1 (0.7)	
Unknown	1 (0.7)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.1.107.3.1: Total, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	252 (100.0)	126 (100.0)
Antibiotics		
Yes	107 (42.5)	44 (34.9)
No	138 (54.8)	74 (58.7)
Unknown	7 (2.8)	8 (6.3)
Azathioprine		
Yes	13 (5.2)	12 (9.5)
More than 12 weeks?		
Yes	5 (2.0)	8 (6.3)
No	5 (2.0)	2 (1.6)
Unknown	3 (1.2)	2 (1.6)
Reason for discontinuation		
Inadequate efficacy	9 (3.6)	9 (7.1)
Other	1 (0.4)	1 (0.8)
Side effects	3 (1.2)	2 (1.6)
No	234 (92.9)	112 (88.9)
Reason for not using		
Contraindications	3 (1.2)	2 (1.6)
Risk of side effects	27 (10.7)	16 (12.7)
Other	204 (81.0)	94 (74.6)
Unknown	5 (2.0)	2 (1.6)
Calcineurin inhibitors		
Yes	127 (50.4)	68 (54.0)
No	114 (45.2)	54 (42.9)
Unknown	10 (4.0)	4 (3.2)
Cyclosporine		
Yes	75 (29.8)	42 (33.3)
More than 12 weeks?		
Yes	60 (23.8)	34 (27.0)
No	13 (5.2)	4 (3.2)
Unknown	2 (0.8)	4 (3.2)
Reason for discontinuation		
Inadequate efficacy	42 (16.7)	19 (15.1)
Other	13 (5.2)	12 (9.5)
Side effects	19 (7.5)	11 (8.7)
No	168 (66.7)	79 (62.7)
Reason for not using		
Contraindications	15 (6.0)	3 (2.4)
Risk of side effects	50 (19.8)	30 (23.8)
Other	103 (40.9)	46 (36.5)
Unknown	9 (3.6)	5 (4.0)
Methotrexate		
Yes	29 (11.5)	30 (23.8)
More than 12 weeks?		
Yes	16 (6.3)	13 (10.3)
No	5 (2.0)	9 (7.1)
Unknown	8 (3.2)	8 (6.3)
Reason for discontinuation		
Inadequate efficacy	11 (4.4)	11 (8.7)
Other	12 (4.8)	14 (11.1)
Side effects	6 (2.4)	5 (4.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.1.107.3.1: Total, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	216 (85.7)	95 (75.4)
Reason for not using		
Contraindications	4 (1.6)	2 (1.6)
Risk of side effects	19 (7.5)	10 (7.9)
Other	193 (76.6)	83 (65.9)
Unknown	7 (2.8)	1 (0.8)
Monoclonal antibody/Dupilumab		
Yes	14 (5.6)	10 (7.9)
No	235 (93.3)	114 (90.5)
Unknown	2 (0.8)	2 (1.6)
Mycophenolate		
Yes	7 (2.8)	5 (4.0)
More than 12 weeks?		
Yes	2 (0.8)	1 (0.8)
No	2 (0.8)	2 (1.6)
Unknown	3 (1.2)	2 (1.6)
Reason for discontinuation		
Inadequate efficacy	3 (1.2)	4 (3.2)
Other	1 (0.4)	1 (0.8)
Side effects	2 (0.8)	
No	235 (93.3)	116 (92.1)
Reason for not using		
Contraindications	3 (1.2)	2 (1.6)
Risk of side effects	25 (9.9)	16 (12.7)
Other	207 (82.1)	98 (77.8)
Unknown	10 (4.0)	5 (4.0)
Other immunosuppressant		
Yes	6 (2.4)	
No	241 (95.6)	121 (96.0)
Unknown	5 (2.0)	5 (4.0)
Phototherapy		
Yes	122 (48.4)	52 (41.3)
No	125 (49.6)	73 (57.9)
Unknown	5 (2.0)	1 (0.8)
Systemic steroids		
Yes	147 (58.3)	85 (67.5)
No	100 (39.7)	37 (29.4)
Unknown	5 (2.0)	4 (3.2)
Topical corticosteroids		
Yes	250 (99.2)	121 (96.0)
Highest potency		
High	131 (52.0)	57 (45.2)
Low	6 (2.4)	1 (0.8)
Moderate	48 (19.0)	29 (23.0)
Ultra high	55 (21.8)	29 (23.0)
Unknown	10 (4.0)	5 (4.0)
No	2 (0.8)	5 (4.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.1.107.3.1: Total, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Wet wraps		
Yes	34 (13.5)	15 (11.9)
No	206 (81.7)	105 (83.3)
Unknown	12 (4.8)	6 (4.8)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.1.107.4.1: Total, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	138 (100.0)	137 (100.0)
Antibiotics		
Yes	55 (39.9)	66 (48.2)
No	76 (55.1)	62 (45.3)
Unknown	7 (5.1)	9 (6.6)
Azathioprine		
Yes	18 (13.0)	18 (13.1)
More than 12 weeks?		
Yes	13 (9.4)	12 (8.8)
No	4 (2.9)	3 (2.2)
Unknown	1 (0.7)	3 (2.2)
Reason for discontinuation		
Inadequate efficacy	12 (8.7)	14 (10.2)
Other	1 (0.7)	2 (1.5)
Side effects	5 (3.6)	2 (1.5)
No	114 (82.6)	116 (84.7)
Reason for not using		
Contraindications	5 (3.6)	10 (7.3)
Risk of side effects	44 (31.9)	33 (24.1)
Other	65 (47.1)	73 (53.3)
Unknown	6 (4.3)	3 (2.2)
Cyclosporine		
Yes	104 (75.4)	102 (74.5)
More than 12 weeks?		
Yes	70 (50.7)	71 (51.8)
No	34 (24.6)	30 (21.9)
Unknown		1 (0.7)
Reason for discontinuation		
Treatment duration >	5 (3.6)	7 (5.1)
Inadequate efficacy	51 (37.0)	43 (31.4)
Other	7 (5.1)	7 (5.1)
Side effects	41 (29.7)	45 (32.8)
No	34 (24.6)	35 (25.5)
Reason for not using		
Contraindications	28 (20.3)	24 (17.5)
Risk of side effects	4 (2.9)	4 (2.9)
Other	2 (1.4)	7 (5.1)
Methotrexate		
Yes	23 (16.7)	26 (19.0)
More than 12 weeks?		
Yes	15 (10.9)	18 (13.1)
No	8 (5.8)	7 (5.1)
Unknown		1 (0.7)
Reason for discontinuation		
Inadequate efficacy	15 (10.9)	18 (13.1)
Other	1 (0.7)	2 (1.5)
Side effects	7 (5.1)	6 (4.4)
No	113 (81.9)	109 (79.6)
Reason for not using		
Contraindications	11 (8.0)	12 (8.8)
Risk of side effects	39 (28.3)	32 (23.4)
Other	63 (45.7)	65 (47.4)
Unknown	2 (1.4)	2 (1.5)
Monoclonal antibody/Dupilumab		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.1.107.4.1: Total, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	9 (6.5)	12 (8.8)
No	127 (92.0)	124 (90.5)
Unknown	2 (1.4)	1 (0.7)
Mycophenolate		
Yes	3 (2.2)	5 (3.6)
More than 12 weeks?		
Yes	3 (2.2)	1 (0.7)
No		4 (2.9)
Reason for discontinuation		
Inadequate efficacy	3 (2.2)	3 (2.2)
Side effects		2 (1.5)
No	127 (92.0)	129 (94.2)
Reason for not using		
Contraindications	4 (2.9)	8 (5.8)
Risk of side effects	45 (32.6)	34 (24.8)
Other	77 (55.8)	87 (63.5)
Unknown	8 (5.8)	3 (2.2)
Other immunosuppressant		
Yes	16 (11.6)	12 (8.8)
No	120 (87.0)	123 (89.8)
Unknown	2 (1.4)	2 (1.5)
Phototherapy		
Yes	79 (57.2)	84 (61.3)
No	58 (42.0)	53 (38.7)
Unknown	1 (0.7)	
Systemic steroids		
Yes	97 (70.3)	91 (66.4)
No	36 (26.1)	39 (28.5)
Unknown	5 (3.6)	7 (5.1)
Topical calcineurin inhibitor		
Yes	92 (66.7)	95 (69.3)
No	37 (26.8)	40 (29.2)
Unknown	9 (6.5)	2 (1.5)
Topical corticosteroids		
Yes	138 (100.0)	136 (99.3)
Highest potency		
High	76 (55.1)	54 (39.4)
Low		1 (0.7)
Moderate	10 (7.2)	15 (10.9)
Ultra high	43 (31.2)	63 (46.0)
Unknown	9 (6.5)	3 (2.2)
No		1 (0.7)
Wet wraps		
Yes	25 (18.1)	19 (13.9)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

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Table 1.1.107.4.1: Total, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	104 (75.4)	114 (83.2)
Unknown	9 (6.5)	4 (2.9)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.1.202.3.1: Total, change in EASI, Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	126	126 30.4 (12.78)		252	252 28.8 (11.97)		
Week 2		124 19.8 (12.98)			251 17.0 (11.25)		
Week 2 chg		124 -10.7 (11.46)	-10.22 (0.85)		251 -11.8 (10.37)	-12.02 (0.60)	-1.81 (-3.85, 0.23) 0.083 [-0.17 (-0.38, 0.05)]
Week 4		126 16.8 (13.62)			247 13.2 (10.47)		
Week 4 chg		126 -13.6 (12.25)	-13.10 (0.88)		247 -15.8 (11.28)	-15.87 (0.63)	-2.78 (-4.91, -0.65) 0.011 [-0.24 (-0.45, -0.02)]
Week 6		125 15.2 (13.41)			247 10.7 (9.46)		
Week 6 chg		125 -15.2 (12.09)	-14.69 (0.84)		247 -18.3 (11.21)	-18.31 (0.60)	-3.62 (-5.65, -1.59) <.001 [-0.31 (-0.53, -0.10)]
Week 8		122 13.6 (12.73)			243 9.3 (8.85)		
Week 8 chg		122 -16.7 (11.39)	-15.93 (0.80)		243 -19.8 (11.30)	-19.69 (0.57)	-3.77 (-5.70, -1.83) <.001 [-0.33 (-0.55, -0.11)]
Week 10		118 13.9 (13.56)			237 8.2 (8.42)		
Week 10 chg		118 -16.2 (11.61)	-15.67 (0.84)		237 -20.7 (12.01)	-20.66 (0.59)	-4.98 (-7.01, -2.96) <.001 [-0.42 (-0.64, -0.20)]
Week 12		119 12.9 (12.82)			238 8.0 (9.27)		
Week 12 chg		119 -17.2 (11.92)	-16.63 (0.86)		238 -21.1 (12.42)	-21.10 (0.61)	-4.47 (-6.55, -2.38) <.001 [-0.36 (-0.59, -0.14)]

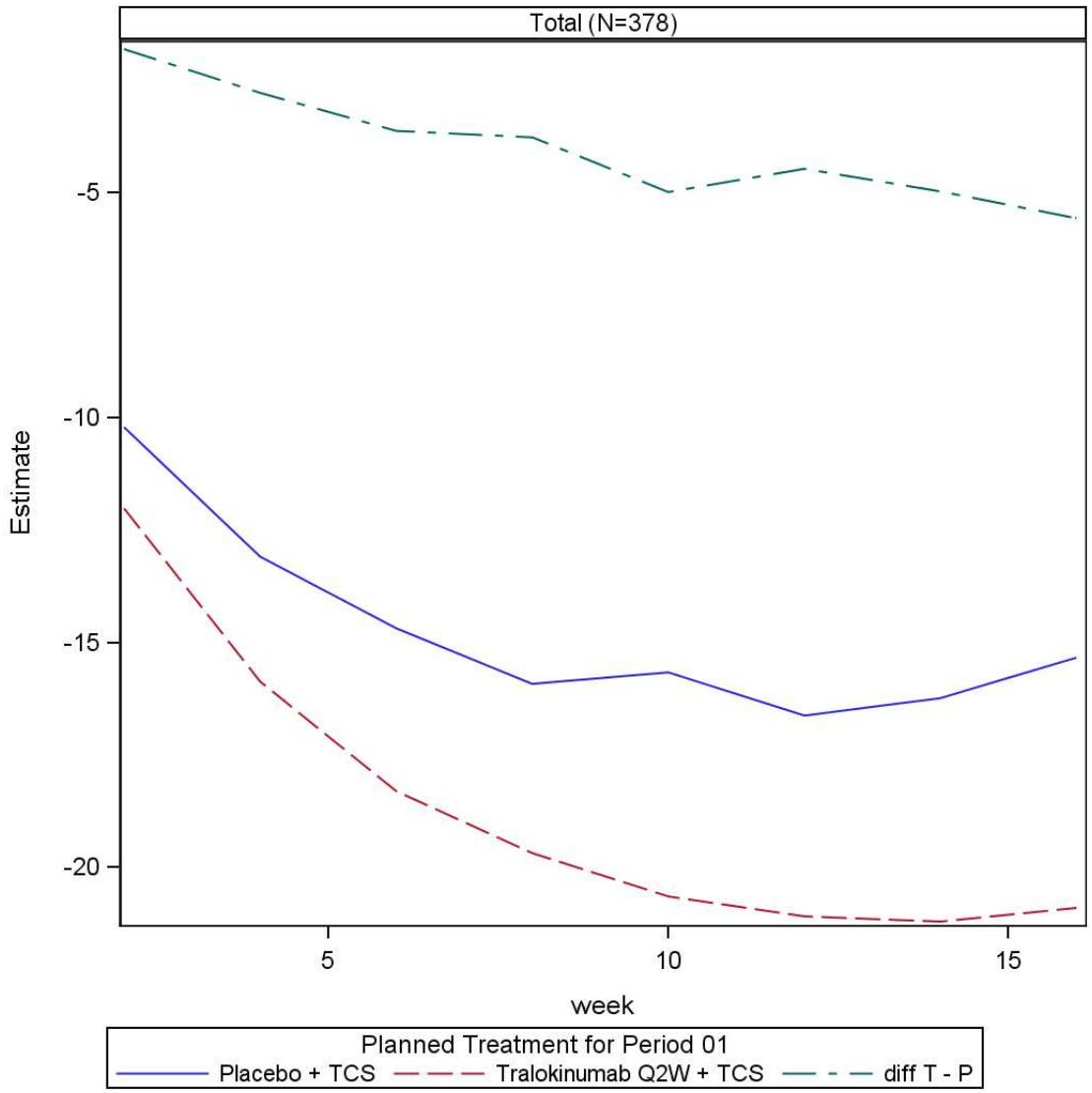
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after 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 an unrestricted covariance model.

Table 1.1.202.3.1: Total, change in EASI, Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	118	13.1 (13.79)		235	7.7 (9.25)		
Week 14 chg	118	-16.9 (13.53)	-16.25 (0.91)	235	-21.4 (12.29)	-21.22 (0.65)	-4.97 (-7.17, -2.77) <.001 [-0.39 (-0.61, -0.17)]
Week 16	123	14.1 (14.89)		241	8.1 (9.15)		
Week 16 chg	123	-16.0 (14.04)	-15.34 (0.95)	241	-20.7 (12.33)	-20.91 (0.68)	-5.57 (-7.86, -3.27) <.001 [-0.43 (-0.65, -0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 an unrestricted covariance model.

Figure 1.1.202.3.2: Total, change in EASI, Treatment policy, LP0162-1339, 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 an unrestricted covariance model.

Table 1.1.205.3.1: Total, EASI 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	141 (56.0)	20.2 (9.77;30.56)	1.6 (1.21; 2.03)	2.3 (1.46; 3.53)	0.0002	
Placebo + TCS	126	45 (35.7)					

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.

04FEB21 23:28 LP0162-Payer /p_bin_eff1/T_t_total_e05_39_w16.txt

Table 1.1.206.3.1: Total, EASI 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	83 (32.9)	11.4 (2.13;20.71)	1.5 (1.05; 2.25)	1.8 (1.08; 2.92)	0.0216	
Placebo + TCS	126	27 (21.4)					

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.

04FEB21 19:09 LP0162-Payer /p_bin_eff1/T_t_total_e06_39_w16.txt

Table 1.1.209.3.1: Total, SCORAD 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	60 (23.8)	11.1 (3.16;18.98)	1.9 (1.12; 3.12)	2.1 (1.17; 3.84)	0.0117	
Placebo + TCS	126	16 (12.7)					

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.

04FEB21 18:16 LP0162-Payer /p_bin_eff1/T_t_total_e09_39_w16.txt

Table 1.1.210.3.1: Total, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	249	115 (46.2)	9.7 (-0.74;20.16)	1.3 (0.97; 1.65)	1.5 (0.96; 2.32)	0.0738	
Placebo + TCS	126	46 (36.5)					

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.

04FEB21 23:02 LP0162-Payer /p_bin_eff1/T_t_total_e10_39_w16.txt

Table 1.1.211.3.1: Total, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	251	153 (61.0)	17.4 (6.78;27.98)	1.4 (1.12; 1.74)	2.0 (1.30; 3.10)	0.0014	
Placebo + TCS	126	55 (43.7)					

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.

Table 1.1.213.3.1: Total, POEM improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	250	199 (79.6)	16.2 (6.28;26.17)	1.3 (1.08; 1.46)	2.2 (1.38; 3.58)	0.0008	
Placebo + TCS	123	78 (63.4)					

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.

Table 1.1.215.3.1: Total, DLQI 0/1, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	62 (24.6)	12.7 (4.92;20.47)	2.1 (1.23; 3.47)	2.4 (1.31; 4.43)	0.0040	
Placebo + TCS	126	15 (11.9)					

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.

04FEB21 17:12 LP0162-Payer /p_bin_eff1/T_t_total_e15_39_w16.txt

Table 1.1.216.3.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	126	126 7.9 (1.49)		252	251 7.7 (1.51)			
Week 1		125 6.5 (1.78)			248 6.2 (1.90)			
Week 1 chg		125 -1.3 (1.50)	-1.28 (0.13)		248 -1.5 (1.56)	-1.50 (0.09)	-0.22 (-0.54, 0.10) [-0.14 (-0.36, 0.07)]	0.172
Week 2		126 6.0 (2.11)			245 5.5 (2.23)			
Week 2 chg		126 -1.8 (2.00)	-1.79 (0.17)		245 -2.2 (2.02)	-2.19 (0.12)	-0.39 (-0.81, 0.02) [-0.20 (-0.41, 0.02)]	0.065
Week 3		125 5.8 (2.18)			243 5.0 (2.26)			
Week 3 chg		125 -2.0 (2.05)	-1.97 (0.18)		243 -2.6 (2.15)	-2.65 (0.13)	-0.68 (-1.12, -0.25) [-0.32 (-0.54, -0.11)]	0.002
Week 4		120 5.5 (2.39)			244 4.8 (2.29)			
Week 4 chg		120 -2.4 (2.21)	-2.30 (0.19)		244 -2.9 (2.21)	-2.93 (0.13)	-0.63 (-1.09, -0.17) [-0.29 (-0.50, -0.07)]	0.007
Week 5		118 5.2 (2.42)			238 4.5 (2.21)			
Week 5 chg		118 -2.7 (2.31)	-2.60 (0.19)		238 -3.2 (2.19)	-3.18 (0.14)	-0.58 (-1.04, -0.11) [-0.26 (-0.48, -0.04)]	0.015
Week 6		122 5.1 (2.50)			239 4.3 (2.23)			
Week 6 chg		122 -2.7 (2.39)	-2.66 (0.20)		239 -3.3 (2.26)	-3.29 (0.14)	-0.63 (-1.10, -0.15) [-0.27 (-0.49, -0.05)]	0.010

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 an unrestricted covariance model.

Table 1.1.216.3.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	116	4.9 (2.48)		231	4.2 (2.27)		
Week 7 chg	116	-2.9 (2.41)	-2.73 (0.20)	231	-3.5 (2.29)	-3.48 (0.14)	-0.75 (-1.23, -0.26) 0.002 [-0.32 (-0.55, -0.10)]
Week 8	116	4.9 (2.49)		227	4.0 (2.31)		
Week 8 chg	116	-2.9 (2.38)	-2.76 (0.20)	227	-3.6 (2.35)	-3.61 (0.15)	-0.85 (-1.34, -0.35) <.001 [-0.36 (-0.58, -0.13)]
Week 9	116	4.9 (2.53)		235	3.9 (2.24)		
Week 9 chg	116	-3.0 (2.35)	-2.83 (0.20)	235	-3.7 (2.31)	-3.75 (0.14)	-0.93 (-1.40, -0.45) <.001 [-0.40 (-0.62, -0.17)]
Week 10	114	4.8 (2.56)		235	3.8 (2.27)		
Week 10 chg	114	-3.0 (2.45)	-2.90 (0.21)	235	-3.8 (2.43)	-3.81 (0.15)	-0.91 (-1.40, -0.41) <.001 [-0.37 (-0.60, -0.15)]
Week 11	115	4.8 (2.54)		231	3.6 (2.19)		
Week 11 chg	115	-3.0 (2.48)	-2.90 (0.20)	231	-4.0 (2.39)	-4.01 (0.14)	-1.12 (-1.61, -0.63) <.001 [-0.46 (-0.69, -0.23)]
Week 12	115	4.7 (2.55)		234	3.7 (2.15)		
Week 12 chg	115	-3.1 (2.41)	-2.92 (0.20)	234	-3.9 (2.40)	-3.96 (0.14)	-1.04 (-1.53, -0.55) <.001 [-0.43 (-0.66, -0.21)]
Week 13	115	4.8 (2.53)		233	3.6 (2.19)		
Week 13 chg	115	-3.1 (2.37)	-2.94 (0.20)	233	-4.1 (2.44)	-4.12 (0.14)	-1.18 (-1.67, -0.69) <.001 [-0.49 (-0.71, -0.26)]

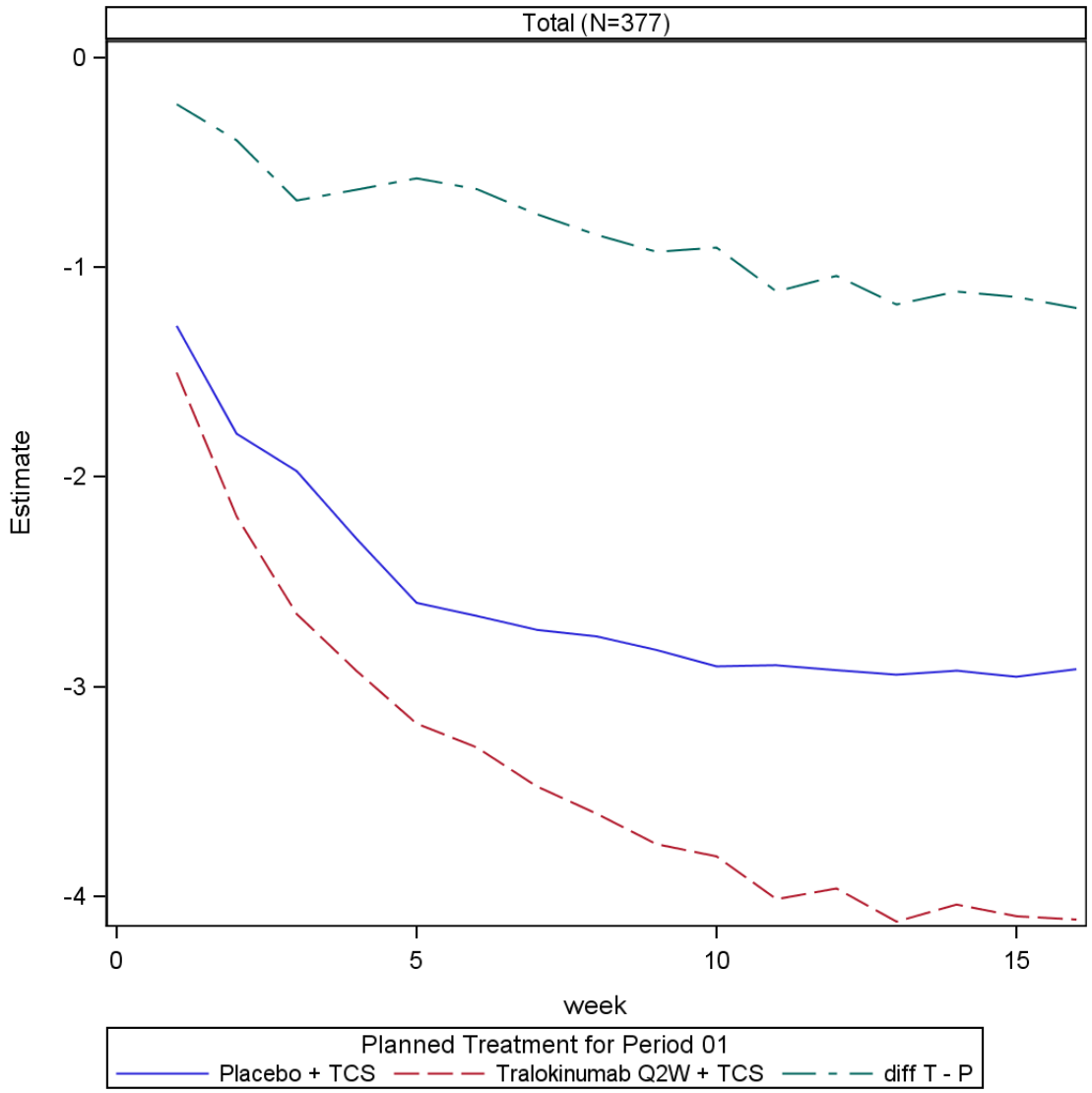
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after 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 an unrestricted covariance model.

Table 1.1.216.3.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	116	4.7 (2.57)		223	3.6 (2.20)			
Week 14 chg	116	-3.1 (2.42)	-2.92 (0.21)	223	-4.0 (2.49)	-4.04 (0.15)	-1.12 (-1.62, -0.62) [-0.45 (-0.68, -0.23)]	<.001
Week 15	114	4.8 (2.59)		225	3.5 (2.20)			
Week 15 chg	114	-3.0 (2.44)	-2.95 (0.21)	225	-4.1 (2.43)	-4.10 (0.15)	-1.14 (-1.64, -0.64) [-0.47 (-0.70, -0.24)]	<.001
Week 16	112	4.7 (2.59)		226	3.5 (2.21)			
Week 16 chg	112	-3.1 (2.51)	-2.92 (0.21)	226	-4.1 (2.42)	-4.11 (0.15)	-1.19 (-1.70, -0.69) [-0.49 (-0.72, -0.26)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 an unrestricted covariance model.

Figure 1.1.216.3.2: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1339, 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 an unrestricted covariance model.

Table 1.1.218.3.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)		
Week 1		125 5.7 (2.39)			248 5.3 (2.33)		
Week 1 chg		125 -1.4 (1.62)	-1.39 (0.14)		248 -1.6 (1.68)	-1.57 (0.10)	-0.18 (-0.52, 0.17) 0.315 [-0.11 (-0.32, 0.11)]
Week 2		126 5.1 (2.66)			245 4.5 (2.54)		
Week 2 chg		126 -1.9 (2.16)	-1.90 (0.19)		245 -2.4 (2.19)	-2.35 (0.13)	-0.46 (-0.90, -0.01) 0.046 [-0.21 (-0.42, 0.01)]
Week 3		125 4.9 (2.61)			243 4.0 (2.57)		
Week 3 chg		125 -2.2 (2.17)	-2.11 (0.19)		243 -2.9 (2.33)	-2.91 (0.14)	-0.79 (-1.26, -0.33) <.001 [-0.35 (-0.57, -0.13)]
Week 4		120 4.6 (2.69)			244 3.8 (2.59)		
Week 4 chg		120 -2.5 (2.26)	-2.42 (0.20)		244 -3.1 (2.41)	-3.15 (0.14)	-0.73 (-1.21, -0.25) 0.003 [-0.31 (-0.53, -0.09)]
Week 5		118 4.3 (2.71)			238 3.4 (2.50)		
Week 5 chg		118 -2.8 (2.32)	-2.68 (0.20)		238 -3.5 (2.40)	-3.48 (0.14)	-0.80 (-1.28, -0.32) 0.001 [-0.34 (-0.56, -0.11)]
Week 6		122 4.3 (2.76)			239 3.2 (2.50)		
Week 6 chg		122 -2.7 (2.43)	-2.68 (0.21)		239 -3.6 (2.53)	-3.60 (0.15)	-0.92 (-1.43, -0.42) <.001 [-0.37 (-0.59, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 an unrestricted covariance model.

Table 1.1.218.3.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	116	4.0 (2.76)		231	3.0 (2.47)		
Week 7 chg	116	-3.0 (2.49)	-2.90 (0.21)	231	-3.8 (2.52)	-3.80 (0.15)	-0.90 (-1.40, -0.40) <.001 [-0.36 (-0.58, -0.13)]
Week 8	116	4.0 (2.72)		227	3.0 (2.49)		
Week 8 chg	116	-3.0 (2.48)	-2.87 (0.21)	227	-3.9 (2.52)	-3.86 (0.15)	-0.99 (-1.50, -0.48) <.001 [-0.39 (-0.62, -0.17)]
Week 9	116	3.9 (2.78)		235	2.8 (2.36)		
Week 9 chg	116	-3.1 (2.48)	-2.97 (0.20)	235	-4.1 (2.49)	-4.07 (0.14)	-1.09 (-1.58, -0.60) <.001 [-0.44 (-0.67, -0.22)]
Week 10	114	3.9 (2.81)		235	2.7 (2.40)		
Week 10 chg	114	-3.1 (2.56)	-3.02 (0.21)	235	-4.1 (2.59)	-4.11 (0.15)	-1.09 (-1.59, -0.58) <.001 [-0.42 (-0.65, -0.20)]
Week 11	115	3.8 (2.71)		231	2.6 (2.33)		
Week 11 chg	115	-3.2 (2.54)	-3.04 (0.21)	231	-4.2 (2.58)	-4.21 (0.15)	-1.16 (-1.66, -0.66) <.001 [-0.45 (-0.68, -0.23)]
Week 12	115	3.8 (2.78)		234	2.7 (2.32)		
Week 12 chg	115	-3.2 (2.59)	-3.03 (0.21)	234	-4.2 (2.61)	-4.19 (0.15)	-1.15 (-1.66, -0.65) <.001 [-0.44 (-0.67, -0.22)]
Week 13	115	3.9 (2.80)		233	2.5 (2.33)		
Week 13 chg	115	-3.2 (2.52)	-3.10 (0.21)	233	-4.4 (2.66)	-4.39 (0.15)	-1.29 (-1.79, -0.78) <.001 [-0.49 (-0.72, -0.27)]

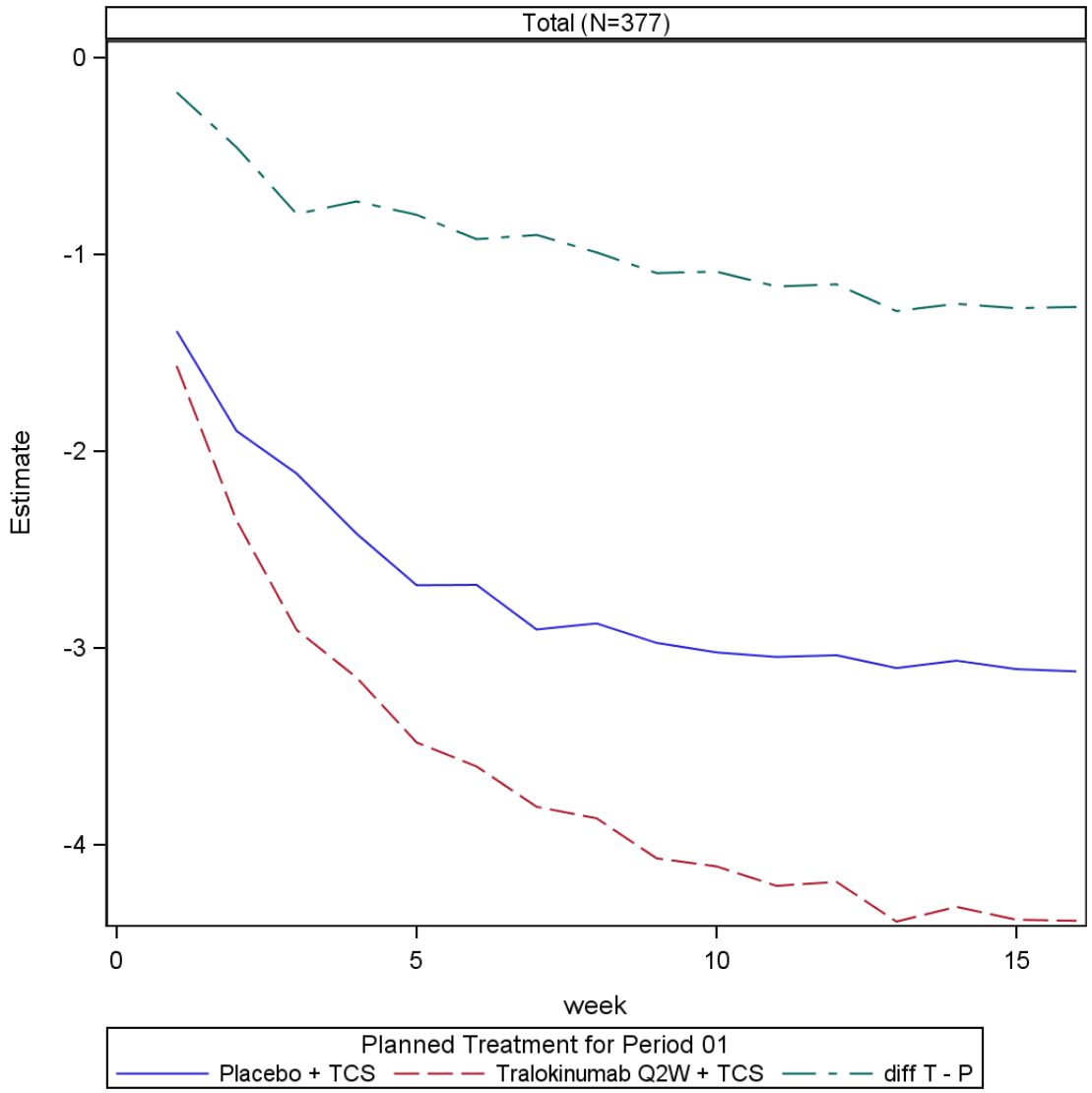
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after 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 an unrestricted covariance model.

Table 1.1.218.3.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	116	3.8 (2.86)		223	2.5 (2.29)			
Week 14 chg	116	-3.2 (2.61)	-3.06 (0.21)	223	-4.3 (2.69)	-4.31 (0.15)	-1.25 (-1.77, -0.73) [-0.47 (-0.70, -0.24)]	<.001
Week 15	114	3.8 (2.87)		225	2.4 (2.27)			
Week 15 chg	114	-3.2 (2.56)	-3.11 (0.21)	225	-4.4 (2.64)	-4.38 (0.15)	-1.27 (-1.78, -0.77) [-0.49 (-0.72, -0.26)]	<.001
Week 16	112	3.7 (2.86)		226	2.4 (2.25)			
Week 16 chg	112	-3.3 (2.59)	-3.12 (0.21)	226	-4.4 (2.62)	-4.38 (0.15)	-1.27 (-1.78, -0.76) [-0.48 (-0.71, -0.26)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 an unrestricted covariance model.

Figure 1.1.218.3.2: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1339, 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 an unrestricted covariance model.

Table 1.1.220.3.1: Total, change in SCORAD, Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)		
Week 2		124 51.4 (17.14)			250 46.5 (16.69)		
Week 2 chg		124 -17.3 (16.94)	-16.78 (1.33)		250 -20.5 (14.91)	-20.64 (0.93)	-3.86 (-7.05, -0.67) 0.018 [-0.25 (-0.46, -0.03)]
Week 4		126 46.6 (20.16)			246 40.1 (16.71)		
Week 4 chg		126 -22.3 (19.12)	-21.71 (1.44)		246 -26.9 (15.62)	-26.91 (1.02)	-5.20 (-8.67, -1.73) 0.003 [-0.31 (-0.52, -0.09)]
Week 6		125 43.6 (20.47)			247 35.7 (16.22)		
Week 6 chg		125 -25.2 (18.79)	-24.73 (1.43)		247 -31.2 (15.78)	-31.13 (1.02)	-6.40 (-9.85, -2.94) <.001 [-0.38 (-0.60, -0.16)]
Week 8		122 41.9 (19.17)			243 32.7 (16.17)		
Week 8 chg		122 -26.8 (17.76)	-25.96 (1.42)		243 -34.2 (16.42)	-34.11 (1.00)	-8.14 (-11.6, -4.72) <.001 [-0.48 (-0.70, -0.26)]
Week 10		118 40.4 (20.53)			236 30.2 (16.85)		
Week 10 chg		118 -28.0 (19.22)	-27.31 (1.54)		236 -36.5 (18.20)	-36.32 (1.09)	-9.01 (-12.7, -5.29) <.001 [-0.49 (-0.71, -0.26)]
Week 12		119 39.6 (21.65)			238 29.4 (17.23)		
Week 12 chg		119 -28.8 (20.95)	-28.17 (1.61)		238 -37.6 (18.51)	-37.57 (1.14)	-9.40 (-13.3, -5.52) <.001 [-0.49 (-0.71, -0.26)]

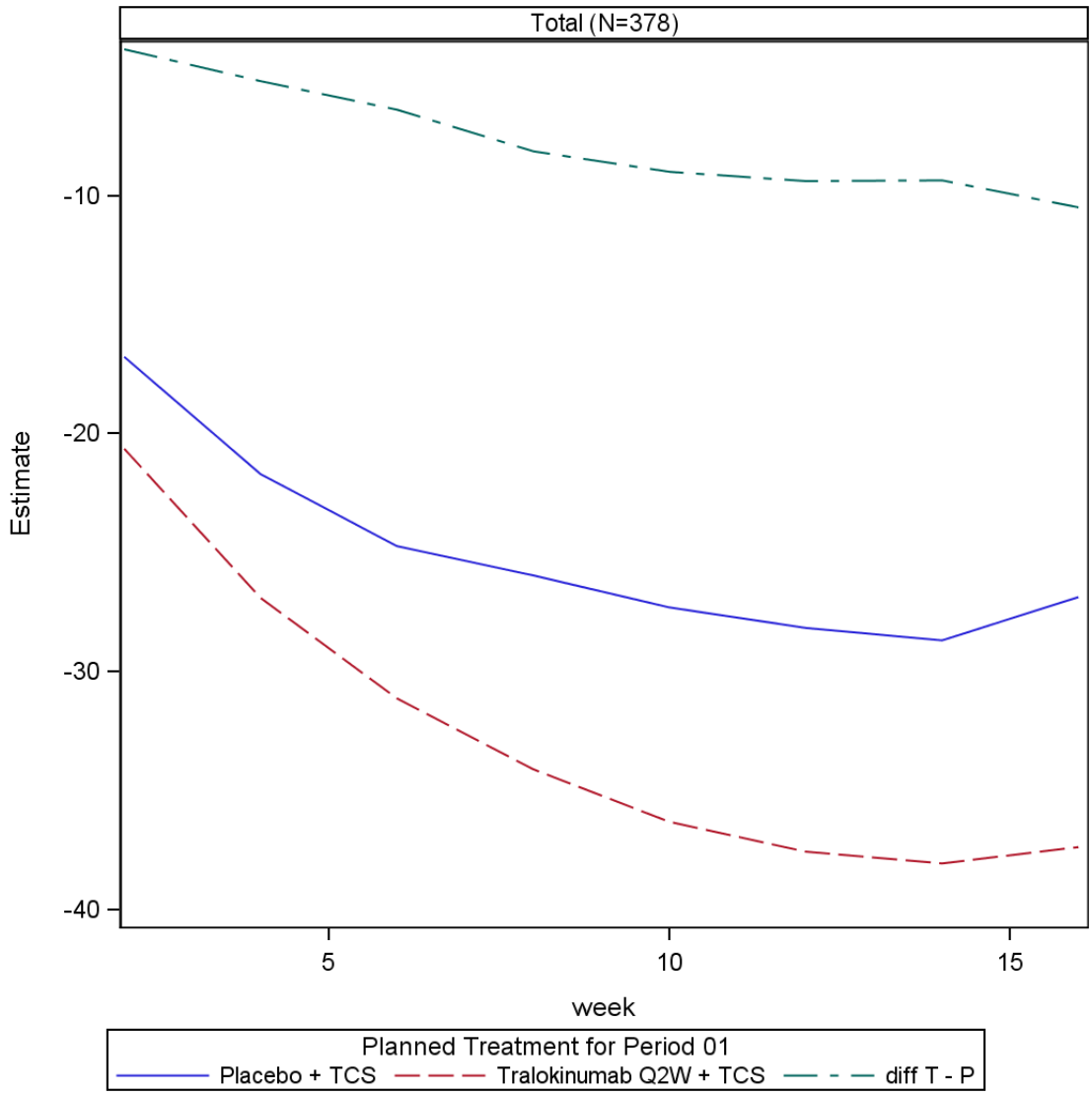
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after 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 an unrestricted covariance model.

Table 1.1.220.3.1: Total, change in SCORAD, Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	38.8 (22.39)		235	28.5 (18.20)			
Week 14 chg	118	-29.6 (21.97)	-28.69 (1.69)	235	-38.4 (18.95)	-38.06 (1.20)	-9.37 (-13.4, -5.29) [-0.47 (-0.69, -0.24)]	<.001
Week 16	122	40.9 (23.52)		241	29.4 (18.62)			
Week 16 chg	122	-27.7 (22.50)	-26.87 (1.73)	241	-37.4 (19.31)	-37.38 (1.23)	-10.50 (-14.7, -6.31) [-0.51 (-0.73, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 an unrestricted covariance model.

Figure 1.1.220.3.2: Total, change in SCORAD, Treatment policy, LP0162-1339, Week 16



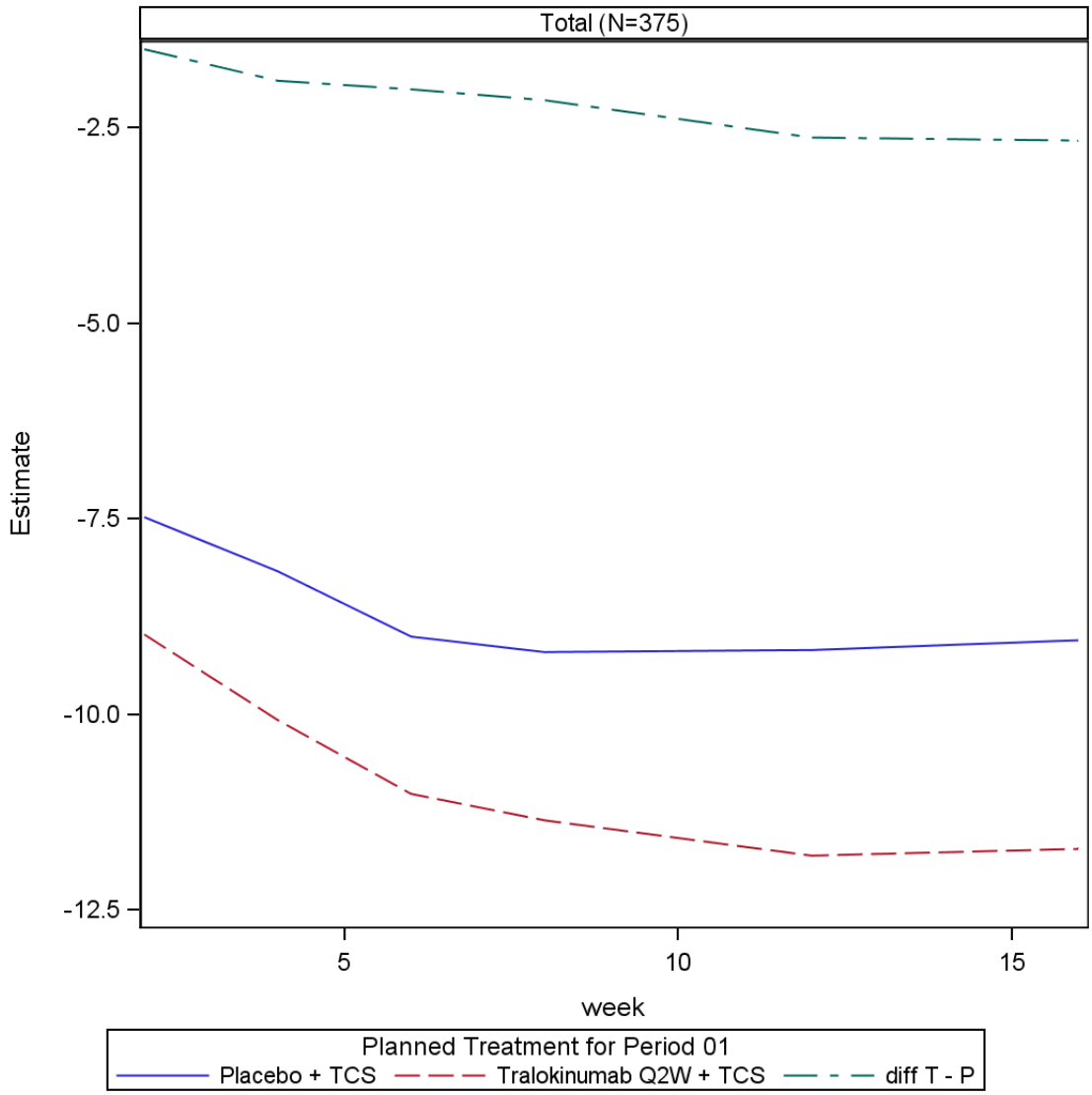
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline 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 an unrestricted covariance model.

Table 1.1.222.3.1: Total, change in DLQI, Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score										
Total										
Baseline	126	125	17.2 (7.15)		252	250	17.6 (7.07)			
Week 2		121	9.8 (7.21)			249	8.6 (6.22)			
Week 2 chg		121	-7.3 (6.72)	-7.48 (0.53)		249	-9.0 (7.25)	-8.98 (0.37)	-1.50 (-2.76, -0.24) [-0.21 (-0.43, 0.01)]	0.020
Week 4		122	9.1 (7.39)			245	7.4 (6.28)			
Week 4 chg		122	-8.1 (7.14)	-8.17 (0.55)		245	-10.2 (7.54)	-10.08 (0.39)	-1.90 (-3.22, -0.58) [-0.26 (-0.47, -0.04)]	0.005
Week 6		123	8.4 (6.88)			242	6.3 (5.75)			
Week 6 chg		123	-8.8 (6.70)	-9.01 (0.51)		242	-11.3 (7.41)	-11.02 (0.36)	-2.01 (-3.23, -0.79) [-0.28 (-0.50, -0.06)]	0.001
Week 8		120	8.1 (6.80)			239	6.2 (5.71)			
Week 8 chg		120	-9.1 (7.09)	-9.21 (0.52)		239	-11.6 (7.90)	-11.36 (0.37)	-2.15 (-3.40, -0.90) [-0.28 (-0.50, -0.06)]	<.001
Week 12		116	7.9 (7.06)			227	5.7 (5.50)			
Week 12 chg		116	-9.0 (7.22)	-9.18 (0.53)		227	-11.9 (7.98)	-11.81 (0.38)	-2.63 (-3.91, -1.35) [-0.34 (-0.56, -0.11)]	<.001
Week 16		119	8.4 (7.30)			237	5.7 (6.02)			
Week 16 chg		119	-8.8 (7.09)	-9.06 (0.54)		237	-11.8 (7.57)	-11.72 (0.38)	-2.67 (-3.97, -1.37) [-0.36 (-0.58, -0.14)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 an unrestricted covariance model.

Figure 1.1.222.3.2: Total, change in DLQI, Treatment policy, LP0162-1339, Week 16



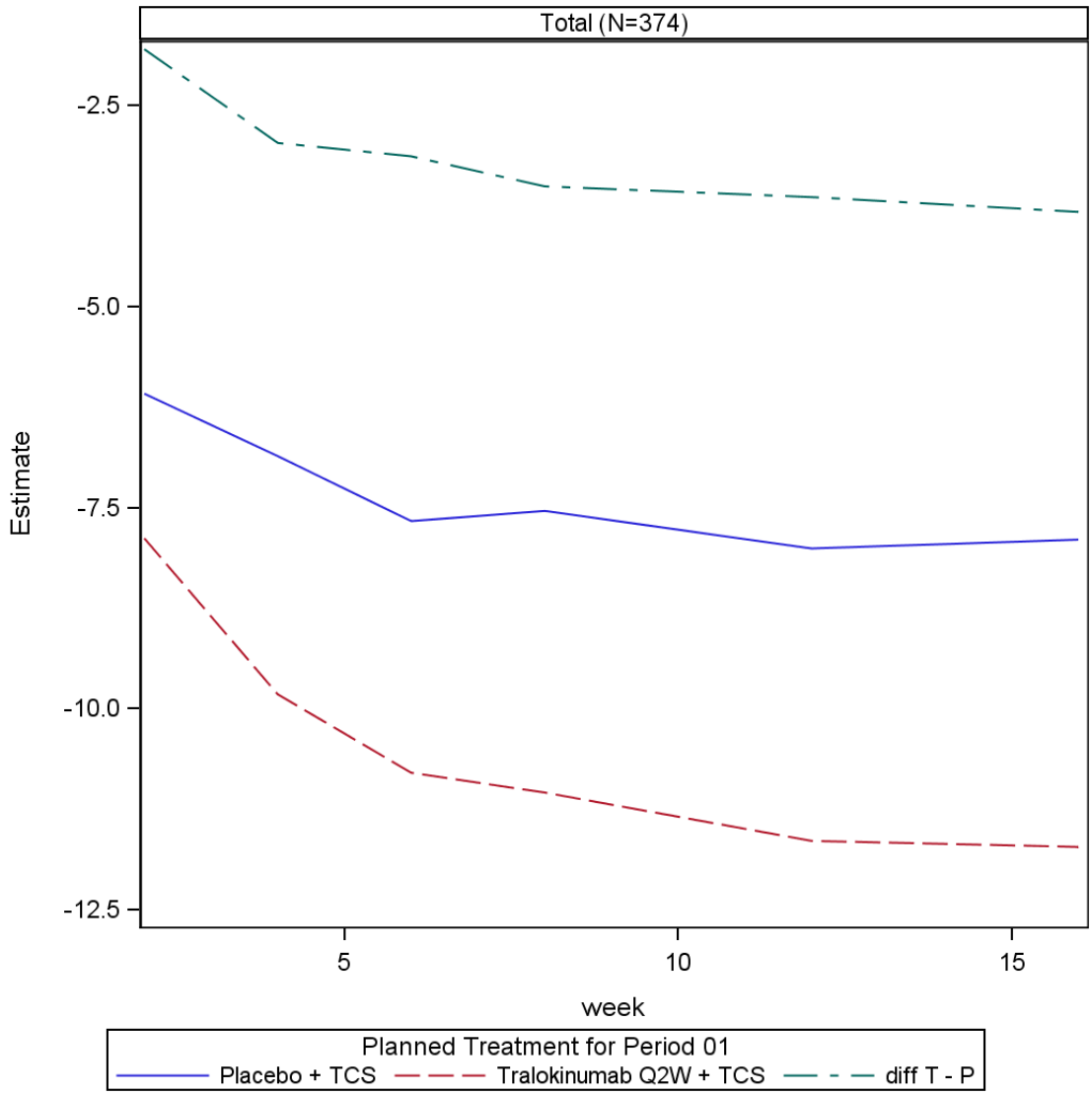
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments 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 an unrestricted covariance model.

Table 1.1.223.3.1: Total, change in POEM, Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total									
Total									
Baseline	126	124	22.4 (5.63)		252	250	22.3 (5.09)		
Week 2		120	16.2 (7.55)			248	14.4 (6.85)		
Week 2 chg		120	-6.1 (6.67)	-6.08 (0.57)		248	-7.8 (6.57)	-7.88 (0.40)	-1.80 (-3.17, -0.43) 0.010 [-0.27 (-0.49, -0.05)]
Week 4		121	15.5 (7.82)			244	12.5 (6.95)		
Week 4 chg		121	-6.8 (7.00)	-6.86 (0.60)		244	-9.8 (7.02)	-9.82 (0.42)	-2.96 (-4.40, -1.53) <.001 [-0.42 (-0.64, -0.20)]
Week 6		122	14.7 (7.89)			242	11.4 (6.75)		
Week 6 chg		122	-7.7 (7.44)	-7.67 (0.60)		242	-10.9 (6.87)	-10.80 (0.42)	-3.13 (-4.57, -1.69) <.001 [-0.44 (-0.66, -0.22)]
Week 8		119	14.6 (7.88)			239	11.2 (7.08)		
Week 8 chg		119	-7.7 (7.38)	-7.54 (0.63)		239	-11.1 (7.24)	-11.04 (0.44)	-3.50 (-5.01, -2.00) <.001 [-0.48 (-0.70, -0.26)]
Week 12		115	14.0 (8.12)			227	10.6 (6.62)		
Week 12 chg		115	-8.2 (7.71)	-8.01 (0.61)		227	-11.6 (6.72)	-11.65 (0.43)	-3.64 (-5.11, -2.17) <.001 [-0.51 (-0.74, -0.29)]
Week 16		118	14.7 (8.27)			237	10.5 (7.20)		
Week 16 chg		118	-7.8 (7.40)	-7.90 (0.64)		237	-11.7 (7.37)	-11.72 (0.45)	-3.82 (-5.37, -2.27) <.001 [-0.52 (-0.74, -0.29)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 an unrestricted covariance model.

Figure 1.1.223.3.2: Total, change in POEM, Treatment policy, LP0162-1339, 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 an unrestricted covariance model.

Table 1.1.273.3.1: Total, SCORAD 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	21 (8.3)	2.0 (-3.46; 7.39)	1.3 (0.60; 2.85)	1.3 (0.57; 3.14)	0.4989	
Placebo + TCS	126	8 (6.3)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

Table 1.1.274.3.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss										
Total										
Baseline	126	126	6.9 (2.72)		252	252	6.5 (2.77)			
Week 2		124	4.4 (3.05)			250	3.7 (2.95)			
Week 2 chg		124	-2.5 (2.93)	-2.36 (0.24)		250	-2.8 (2.95)	-2.86 (0.17)	-0.49 (-1.06, 0.08) [-0.17 (-0.38, 0.05)]	0.089
Week 4		126	3.7 (3.07)			246	3.1 (2.84)			
Week 4 chg		126	-3.1 (3.14)	-2.96 (0.24)		246	-3.3 (3.01)	-3.36 (0.17)	-0.40 (-0.98, 0.17) [-0.13 (-0.35, 0.08)]	0.169
Week 6		125	3.4 (2.99)			247	2.7 (2.75)			
Week 6 chg		125	-3.5 (3.05)	-3.31 (0.23)		247	-3.7 (3.04)	-3.72 (0.17)	-0.41 (-0.97, 0.16) [-0.13 (-0.35, 0.08)]	0.157
Week 8		122	3.4 (3.15)			243	2.5 (2.71)			
Week 8 chg		122	-3.4 (3.28)	-3.25 (0.24)		243	-3.9 (2.98)	-3.96 (0.17)	-0.72 (-1.29, -0.14) [-0.23 (-0.45, -0.01)]	0.015
Week 10		118	3.2 (2.97)			236	2.3 (2.60)			
Week 10 chg		118	-3.6 (3.11)	-3.45 (0.23)		236	-4.1 (3.15)	-4.17 (0.16)	-0.72 (-1.28, -0.16) [-0.23 (-0.45, -0.01)]	0.012
Week 12		119	3.1 (3.11)			238	2.2 (2.57)			
Week 12 chg		119	-3.7 (3.14)	-3.55 (0.24)		238	-4.2 (3.15)	-4.26 (0.17)	-0.71 (-1.27, -0.14) [-0.22 (-0.45, -0.00)]	0.015

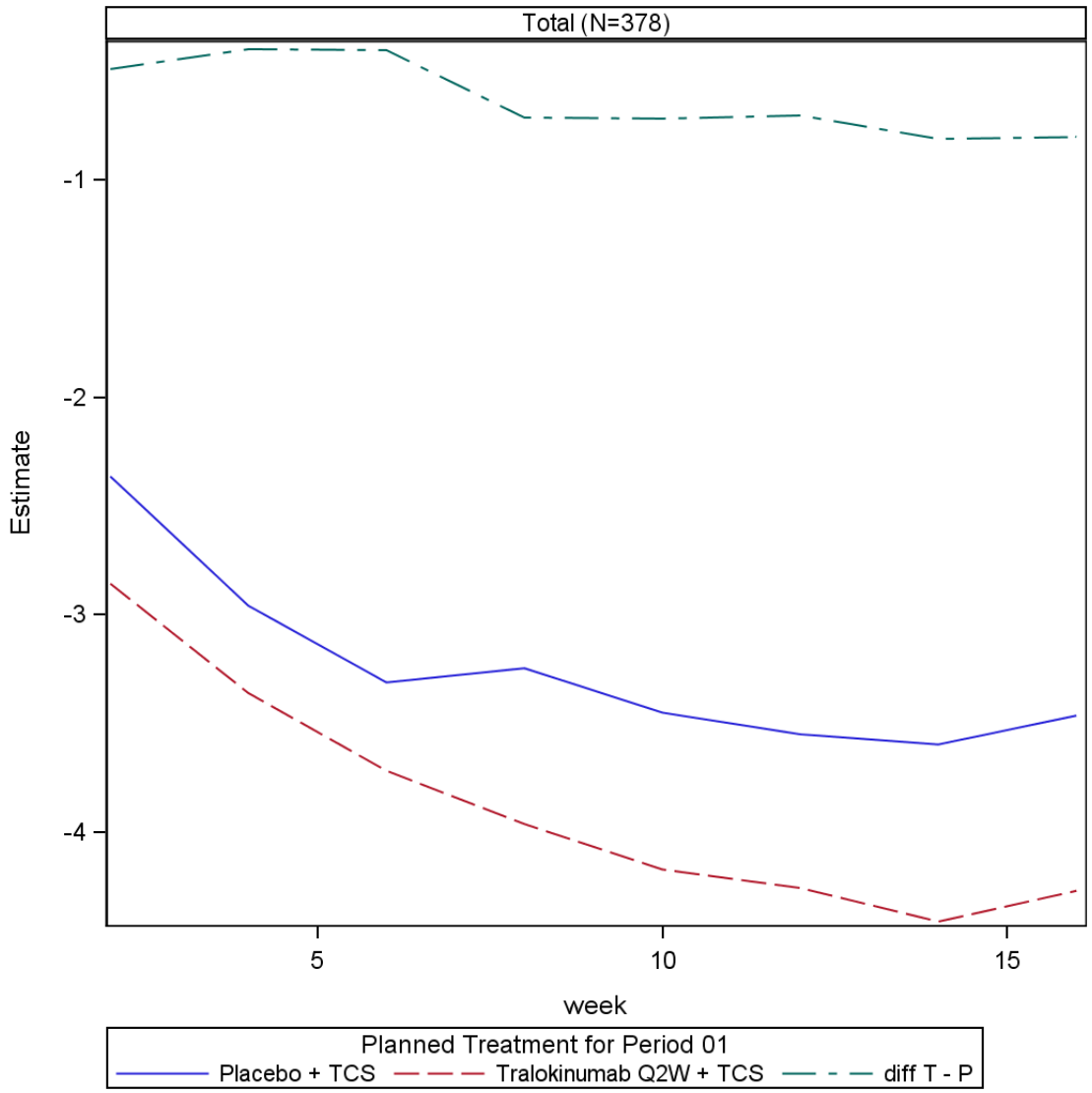
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*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 an unrestricted covariance model.

Table 1.1.274.3.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	3.0 (3.03)		235	2.0 (2.52)			
Week 14 chg	118	-3.8 (3.10)	-3.60 (0.24)	235	-4.4 (3.19)	-4.41 (0.17)	-0.81 (-1.38, -0.25) [-0.26 (-0.48, -0.04)]	0.005
Week 16	122	3.2 (3.24)		241	2.2 (2.68)			
Week 16 chg	122	-3.7 (3.20)	-3.46 (0.25)	241	-4.2 (3.34)	-4.27 (0.18)	-0.81 (-1.40, -0.21) [-0.24 (-0.46, -0.03)]	0.008

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 VAS = Treatment*Week + [Baseline VAS]*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 an unrestricted covariance model.

Figure 1.1.274.3.2: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 an unrestricted covariance model.

Table 1.1.276.3.1: Total, Atopic dermatitis flares, all observed data, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	75.03	70 (27.8)	119	158.60	130.5	187.5	
Placebo + TCS	126	37.94	43 (34.1)	75	197.67	155.0	244.4	

The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. 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. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.1.277.3.1: Total, Atopic dermatitis flares, excluding data after rescue medication, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	74.09	69 (27.4)	113	152.51	125.2	181.5	
Placebo + TCS	126	35.55	40 (31.7)	62	174.42	135.0	222.4	

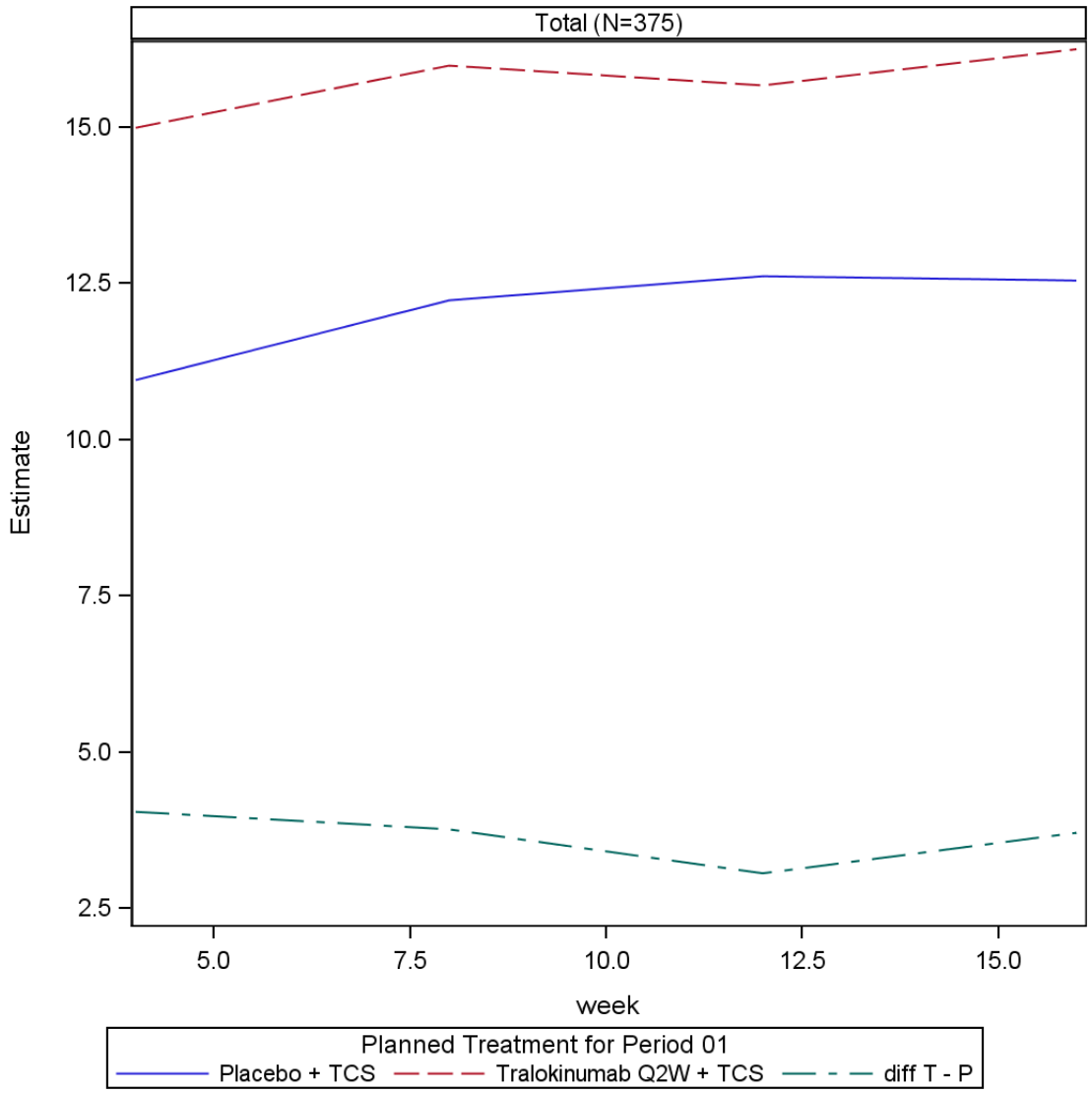
The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. rate/100PYE: number of events per 100 patient years of exposure. Q2W: Every 2 weeks. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.1.278.3.1: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	126	125	59.4 (23.09)		252	250	59.1 (25.01)		
Week 4		122	70.1 (18.94)			249	74.1 (18.34)		
Week 4 chg		122	10.3 (18.72)	10.95 (1.40)		249	15.0 (21.76)	14.99 (0.98)	4.04 (0.69, 7.39) 0.018 [0.19 (-0.02, 0.41)]
Week 8		120	71.2 (20.22)			237	75.5 (18.26)		
Week 8 chg		120	12.1 (23.42)	12.23 (1.58)		237	16.4 (23.73)	15.98 (1.13)	3.76 (-0.07, 7.58) 0.054 [0.16 (-0.06, 0.38)]
Week 12		116	72.3 (21.36)			227	75.1 (18.28)		
Week 12 chg		116	12.1 (23.53)	12.61 (1.64)		227	16.4 (23.72)	15.67 (1.17)	3.05 (-0.90, 7.00) 0.129 [0.13 (-0.09, 0.35)]
Week 16		116	71.5 (21.22)			232	75.8 (18.84)		
Week 16 chg		116	12.4 (22.66)	12.54 (1.64)		232	17.0 (24.19)	16.25 (1.16)	3.70 (-0.25, 7.66) 0.067 [0.16 (-0.07, 0.38)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 VAS = Treatment*Week + [Baseline VAS]*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 an unrestricted covariance model.

Figure 1.1.278.3.2: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 an unrestricted covariance model.

Table 1.1.279.3.1: Total, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	126	126 7.9 (1.49)		252	251 7.7 (1.51)			
Week 16		112 4.7 (2.59)			226 3.5 (2.21)			
Week 16 chg		112 -3.1 (2.51)	-3.03 (0.21)		226 -4.1 (2.42)	-4.13 (0.15)	-1.10 (-1.61, -0.58) [-0.45 (-0.68, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.1.280.3.1: Total, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)			
Week 16		112 3.7 (2.86)			226 2.4 (2.25)			
Week 16 chg		112 -3.3 (2.59)	-3.23 (0.22)		226 -4.4 (2.62)	-4.42 (0.15)	-1.19 (-1.72, -0.67) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.1.281.3.1: Total, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)		
Week 16		122 40.9 (23.52)			241 29.4 (18.62)		
Week 16 chg		122 -27.7 (22.50)	-26.93 (1.75)		241 -37.4 (19.31)	-37.74 (1.24)	-10.81 (-15.0, -6.58) <.001 [-0.53 (-0.75, -0.31)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.1.282.3.1: Total, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score										
Total										
Baseline	126	125	17.2 (7.15)		252	250	17.6 (7.07)			
Week 16		120	8.3 (7.27)			239	5.7 (6.00)			
Week 16 chg		119	-8.8 (7.09)	-8.95 (0.55)		237	-11.8 (7.57)	-11.74 (0.39)	-2.78 (-4.10, -1.47) [-0.38 (-0.60, -0.15)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.1.283.3.1: Total, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	126	124 22.4 (5.63)		252	250 22.3 (5.09)			
Week 16		120 14.6 (8.22)			239 10.4 (7.20)			
Week 16 chg		118 -7.8 (7.40)	-7.74 (0.65)		237 -11.7 (7.37)	-11.74 (0.46)	-4.00 (-5.56, -2.44) [-0.54 (-0.77, -0.32)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.1.285.3.1: Total, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	126	125	59.4 (23.09)		252	250	59.1 (25.01)		
Week 16		117	71.5 (21.13)			234	75.8 (18.76)		
Week 16 chg		116	12.4 (22.66)	12.50 (1.65)		232	17.0 (24.19)	16.95 (1.17)	4.45 (0.46, 8.43) 0.029 [0.19 (-0.04, 0.41)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.1.286.3.1: Total, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	126	126 6.9 (2.72)		252	252 6.5 (2.77)		
Week 16		122 3.2 (3.24)			241 2.2 (2.68)		
Week 16 chg		122 -3.7 (3.20)	-3.44 (0.25)		241 -4.2 (3.34)	-4.29 (0.18)	-0.85 (-1.45, -0.25) 0.006 [-0.26 (-0.48, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.1.291.3.1: Total, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	126	126 30.4 (12.78)		252	252 28.8 (11.97)		
Week 2		124 19.8 (12.98)			251 17.0 (11.25)		
Week 2 chg		124 -10.7 (11.46)	-10.25 (0.87)		251 -11.8 (10.37)	-12.03 (0.61)	-1.78 (-3.86, 0.30) 0.094 [-0.17 (-0.38, 0.05)]
Week 4		126 16.8 (13.62)			247 13.2 (10.47)		
Week 4 chg		126 -13.6 (12.25)	-13.09 (0.86)		247 -15.8 (11.28)	-15.88 (0.61)	-2.78 (-4.86, -0.70) 0.009 [-0.24 (-0.45, -0.02)]
Week 6		125 15.2 (13.41)			247 10.7 (9.46)		
Week 6 chg		125 -15.2 (12.09)	-14.70 (0.87)		247 -18.3 (11.21)	-18.31 (0.61)	-3.62 (-5.70, -1.53) <.001 [-0.31 (-0.53, -0.10)]
Week 8		122 13.6 (12.73)			243 9.3 (8.85)		
Week 8 chg		122 -16.7 (11.39)	-15.95 (0.87)		243 -19.8 (11.30)	-19.68 (0.61)	-3.73 (-5.82, -1.64) <.001 [-0.33 (-0.55, -0.11)]
Week 10		118 13.9 (13.56)			237 8.2 (8.42)		
Week 10 chg		118 -16.2 (11.61)	-15.71 (0.87)		237 -20.7 (12.01)	-20.64 (0.62)	-4.92 (-7.03, -2.82) <.001 [-0.41 (-0.64, -0.19)]
Week 12		119 12.9 (12.82)			238 8.0 (9.27)		
Week 12 chg		119 -17.2 (11.92)	-16.57 (0.87)		238 -21.1 (12.42)	-21.12 (0.62)	-4.55 (-6.65, -2.45) <.001 [-0.37 (-0.59, -0.15)]

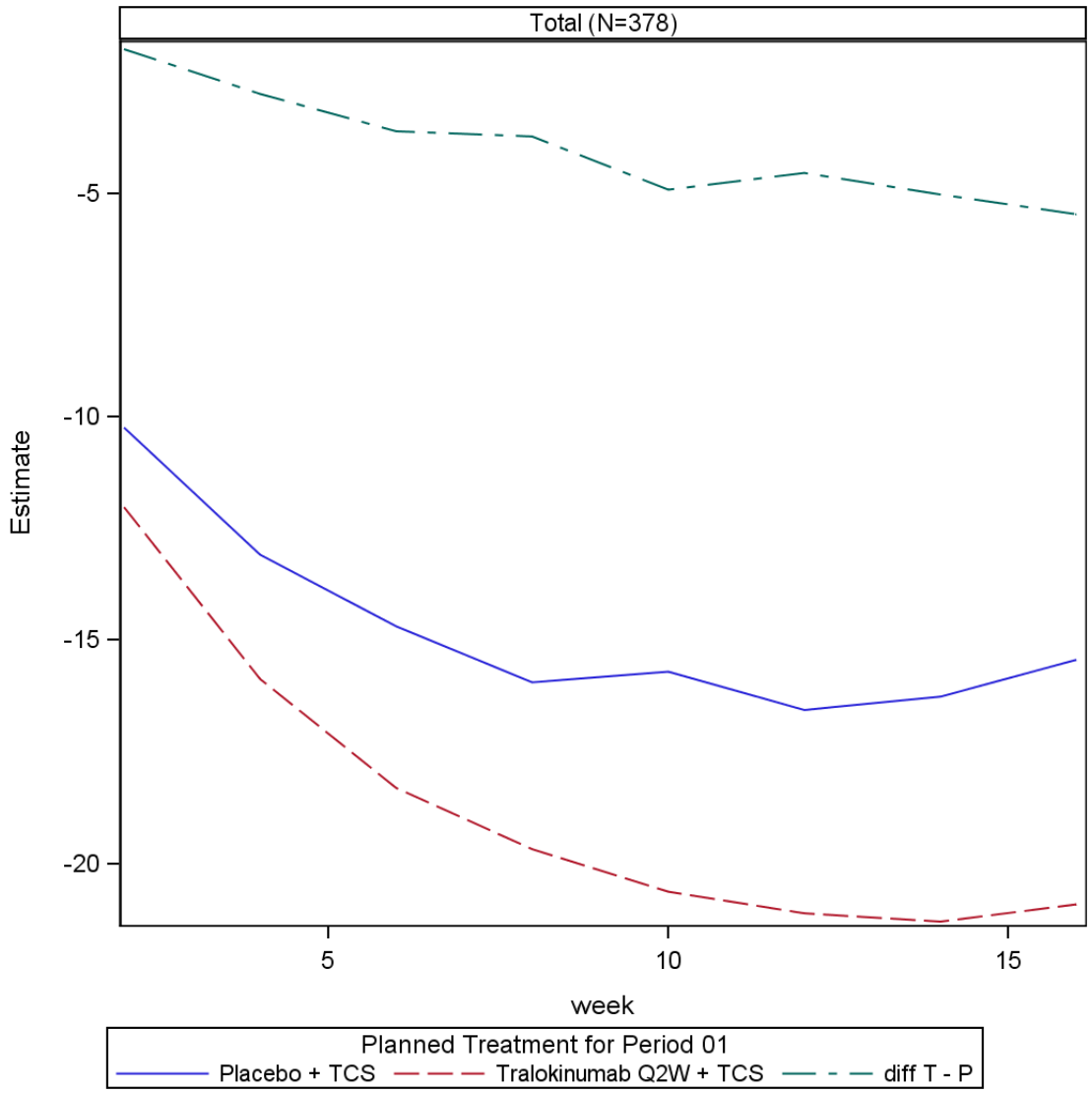
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after 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 1.1.291.3.1: Total, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	13.1 (13.79)		235	7.7 (9.25)			
Week 14 chg	118	-16.9 (13.53)	-16.27 (0.87)	235	-21.4 (12.29)	-21.30 (0.62)	-5.03 (-7.14, -2.93) [-0.40 (-0.62, -0.17)]	<.001
Week 16	123	14.1 (14.89)		241	8.1 (9.15)			
Week 16 chg	123	-16.0 (14.04)	-15.45 (0.87)	241	-20.7 (12.33)	-20.92 (0.62)	-5.47 (-7.56, -3.38) [-0.42 (-0.64, -0.20)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 1.1.291.3.2: Total, change in EASI, Treatment policy estimand, LP0162-1339, 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 1.1.293.3.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	126	126 7.9 (1.49)		252	251 7.7 (1.51)			
Week 1		125 6.5 (1.78)			248 6.2 (1.90)			
Week 1 chg		125 -1.3 (1.50)	-1.27 (0.19)		248 -1.5 (1.56)	-1.50 (0.14)	-0.23 (-0.69, 0.24) [-0.15 (-0.36, 0.07)]	0.336
Week 2		126 6.0 (2.11)			245 5.5 (2.23)			
Week 2 chg		126 -1.8 (2.00)	-1.80 (0.19)		245 -2.2 (2.02)	-2.19 (0.14)	-0.39 (-0.85, 0.07) [-0.19 (-0.41, 0.02)]	0.097
Week 3		125 5.8 (2.18)			243 5.0 (2.26)			
Week 3 chg		125 -2.0 (2.05)	-1.97 (0.19)		243 -2.6 (2.15)	-2.65 (0.14)	-0.68 (-1.15, -0.22) [-0.32 (-0.54, -0.11)]	0.004
Week 4		120 5.5 (2.39)			244 4.8 (2.29)			
Week 4 chg		120 -2.4 (2.21)	-2.31 (0.19)		244 -2.9 (2.21)	-2.92 (0.14)	-0.62 (-1.08, -0.15) [-0.28 (-0.50, -0.06)]	0.009
Week 5		118 5.2 (2.42)			238 4.5 (2.21)			
Week 5 chg		118 -2.7 (2.31)	-2.62 (0.19)		238 -3.2 (2.19)	-3.19 (0.14)	-0.56 (-1.03, -0.10) [-0.25 (-0.47, -0.03)]	0.018
Week 6		122 5.1 (2.50)			239 4.3 (2.23)			
Week 6 chg		122 -2.7 (2.39)	-2.68 (0.19)		239 -3.3 (2.26)	-3.30 (0.14)	-0.62 (-1.08, -0.15) [-0.27 (-0.49, -0.05)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 1.1.293.3.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	116	4.9 (2.48)		231	4.2 (2.27)			
Week 7 chg	116	-2.9 (2.41)	-2.79 (0.19)	231	-3.5 (2.29)	-3.47 (0.14)	-0.68 (-1.15, -0.22) [-0.29 (-0.52, -0.07)]	0.004
Week 8	116	4.9 (2.49)		227	4.0 (2.31)			
Week 8 chg	116	-2.9 (2.38)	-2.81 (0.19)	227	-3.6 (2.35)	-3.60 (0.14)	-0.79 (-1.26, -0.32) [-0.34 (-0.56, -0.11)]	<.001
Week 9	116	4.9 (2.53)		235	3.9 (2.24)			
Week 9 chg	116	-3.0 (2.35)	-2.88 (0.19)	235	-3.7 (2.31)	-3.75 (0.14)	-0.87 (-1.33, -0.40) [-0.37 (-0.60, -0.15)]	<.001
Week 10	114	4.8 (2.56)		235	3.8 (2.27)			
Week 10 chg	114	-3.0 (2.45)	-2.97 (0.19)	235	-3.8 (2.43)	-3.82 (0.14)	-0.85 (-1.31, -0.38) [-0.35 (-0.57, -0.12)]	<.001
Week 11	115	4.8 (2.54)		231	3.6 (2.19)			
Week 11 chg	115	-3.0 (2.48)	-2.96 (0.19)	231	-4.0 (2.39)	-4.03 (0.14)	-1.06 (-1.53, -0.60) [-0.44 (-0.67, -0.21)]	<.001
Week 12	115	4.7 (2.55)		234	3.7 (2.15)			
Week 12 chg	115	-3.1 (2.41)	-2.99 (0.19)	234	-3.9 (2.40)	-3.97 (0.14)	-0.98 (-1.45, -0.51) [-0.41 (-0.63, -0.18)]	<.001
Week 13	115	4.8 (2.53)		233	3.6 (2.19)			
Week 13 chg	115	-3.1 (2.37)	-3.00 (0.19)	233	-4.1 (2.44)	-4.12 (0.14)	-1.12 (-1.59, -0.65) [-0.46 (-0.69, -0.24)]	<.001

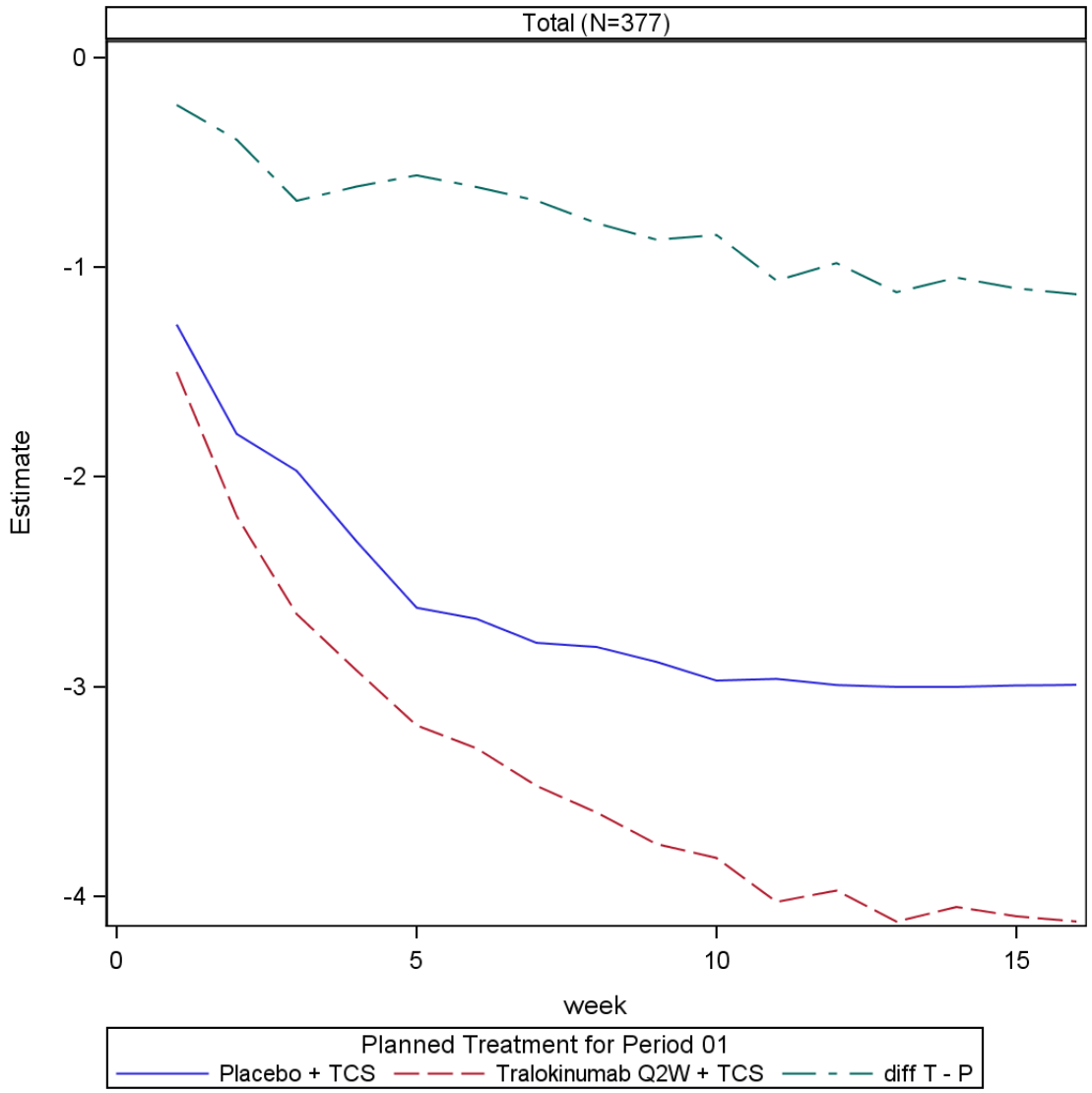
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after 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 1.1.293.3.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	116	4.7 (2.57)		223	3.6 (2.20)			
Week 14 chg	116	-3.1 (2.42)	-3.00 (0.19)	223	-4.0 (2.49)	-4.05 (0.14)	-1.05 (-1.52, -0.58) [-0.43 (-0.65, -0.20)]	<.001
Week 15	114	4.8 (2.59)		225	3.5 (2.20)			
Week 15 chg	114	-3.0 (2.44)	-3.00 (0.19)	225	-4.1 (2.43)	-4.10 (0.14)	-1.10 (-1.57, -0.63) [-0.45 (-0.68, -0.22)]	<.001
Week 16	112	4.7 (2.59)		226	3.5 (2.21)			
Week 16 chg	112	-3.1 (2.51)	-2.99 (0.19)	226	-4.1 (2.42)	-4.12 (0.14)	-1.13 (-1.60, -0.66) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 1.1.293.3.2: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, 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 1.1.295.3.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)			
Week 1		125 5.7 (2.39)			248 5.3 (2.33)			
Week 1 chg		125 -1.4 (1.62)	-1.38 (0.20)		248 -1.6 (1.68)	-1.56 (0.14)	-0.18 (-0.65, 0.30)	0.468
							[-0.11 (-0.32, 0.11)]	
Week 2		126 5.1 (2.66)			245 4.5 (2.54)			
Week 2 chg		126 -1.9 (2.16)	-1.90 (0.20)		245 -2.4 (2.19)	-2.35 (0.14)	-0.45 (-0.93, 0.03)	0.066
							[-0.21 (-0.42, 0.01)]	
Week 3		125 4.9 (2.61)			243 4.0 (2.57)			
Week 3 chg		125 -2.2 (2.17)	-2.11 (0.20)		243 -2.9 (2.33)	-2.90 (0.14)	-0.79 (-1.27, -0.31)	0.001
							[-0.35 (-0.56, -0.13)]	
Week 4		120 4.6 (2.69)			244 3.8 (2.59)			
Week 4 chg		120 -2.5 (2.26)	-2.44 (0.20)		244 -3.1 (2.41)	-3.15 (0.14)	-0.70 (-1.18, -0.22)	0.004
							[-0.30 (-0.52, -0.08)]	
Week 5		118 4.3 (2.71)			238 3.4 (2.50)			
Week 5 chg		118 -2.8 (2.32)	-2.70 (0.20)		238 -3.5 (2.40)	-3.48 (0.14)	-0.78 (-1.26, -0.30)	0.002
							[-0.33 (-0.55, -0.11)]	
Week 6		122 4.3 (2.76)			239 3.2 (2.50)			
Week 6 chg		122 -2.7 (2.43)	-2.70 (0.20)		239 -3.6 (2.53)	-3.61 (0.14)	-0.91 (-1.39, -0.43)	<.001
							[-0.36 (-0.58, -0.14)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 1.1.295.3.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	116	4.0 (2.76)		231	3.0 (2.47)		
Week 7 chg	116	-3.0 (2.49)	-2.97 (0.20)	231	-3.8 (2.52)	-3.81 (0.14)	-0.84 (-1.32, -0.36) <.001 [-0.34 (-0.56, -0.11)]
Week 8	116	4.0 (2.72)		227	3.0 (2.49)		
Week 8 chg	116	-3.0 (2.48)	-2.92 (0.20)	227	-3.9 (2.52)	-3.87 (0.14)	-0.95 (-1.43, -0.47) <.001 [-0.38 (-0.60, -0.15)]
Week 9	116	3.9 (2.78)		235	2.8 (2.36)		
Week 9 chg	116	-3.1 (2.48)	-3.03 (0.20)	235	-4.1 (2.49)	-4.07 (0.14)	-1.04 (-1.52, -0.56) <.001 [-0.42 (-0.64, -0.19)]
Week 10	114	3.9 (2.81)		235	2.7 (2.40)		
Week 10 chg	114	-3.1 (2.56)	-3.09 (0.20)	235	-4.1 (2.59)	-4.11 (0.14)	-1.02 (-1.50, -0.54) <.001 [-0.40 (-0.62, -0.17)]
Week 11	115	3.8 (2.71)		231	2.6 (2.33)		
Week 11 chg	115	-3.2 (2.54)	-3.10 (0.20)	231	-4.2 (2.58)	-4.22 (0.14)	-1.12 (-1.60, -0.64) <.001 [-0.44 (-0.66, -0.21)]
Week 12	115	3.8 (2.78)		234	2.7 (2.32)		
Week 12 chg	115	-3.2 (2.59)	-3.10 (0.20)	234	-4.2 (2.61)	-4.19 (0.14)	-1.09 (-1.57, -0.61) <.001 [-0.42 (-0.64, -0.19)]
Week 13	115	3.9 (2.80)		233	2.5 (2.33)		
Week 13 chg	115	-3.2 (2.52)	-3.16 (0.20)	233	-4.4 (2.66)	-4.39 (0.14)	-1.24 (-1.72, -0.75) <.001 [-0.47 (-0.70, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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.

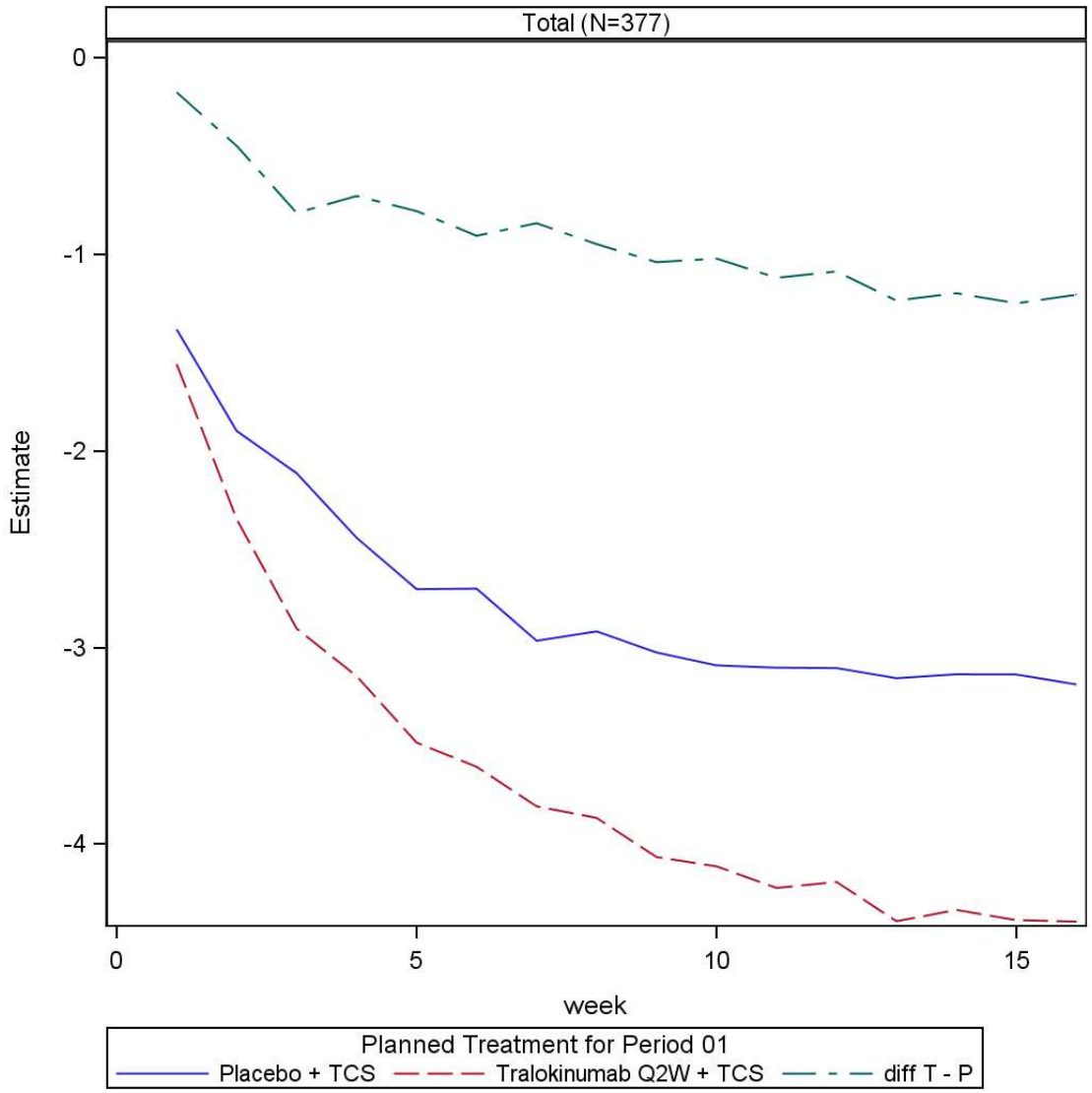
12MAY21 12:08 LP0162-Payer /p_mmrm3/t_t_total_e95_39_w16.txt

Table 1.1.295.3.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	116	3.8 (2.86)		223	2.5 (2.29)			
Week 14 chg	116	-3.2 (2.61)	-3.14 (0.20)	223	-4.3 (2.69)	-4.33 (0.14)	-1.20 (-1.68, -0.72) [-0.45 (-0.68, -0.22)]	<.001
Week 15	114	3.8 (2.87)		225	2.4 (2.27)			
Week 15 chg	114	-3.2 (2.56)	-3.14 (0.20)	225	-4.4 (2.64)	-4.39 (0.14)	-1.25 (-1.73, -0.77) [-0.48 (-0.71, -0.25)]	<.001
Week 16	112	3.7 (2.86)		226	2.4 (2.25)			
Week 16 chg	112	-3.3 (2.59)	-3.19 (0.20)	226	-4.4 (2.62)	-4.39 (0.14)	-1.21 (-1.69, -0.72) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 1.1.295.3.2: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, 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 1.1.297.3.1: Total, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)		
Week 2		124 51.4 (17.14)			250 46.5 (16.69)		
Week 2 chg		124 -17.3 (16.94)	-16.83 (1.52)		250 -20.5 (14.91)	-20.64 (1.07)	-3.81 (-7.47, -0.15) 0.042 [-0.24 (-0.46, -0.03)]
Week 4		126 46.6 (20.16)			246 40.1 (16.71)		
Week 4 chg		126 -22.3 (19.12)	-21.68 (1.52)		246 -26.9 (15.62)	-26.91 (1.08)	-5.23 (-8.89, -1.57) 0.005 [-0.31 (-0.53, -0.09)]
Week 6		125 43.6 (20.47)			247 35.7 (16.22)		
Week 6 chg		125 -25.2 (18.79)	-24.72 (1.52)		247 -31.2 (15.78)	-31.15 (1.08)	-6.43 (-10.1, -2.76) <.001 [-0.38 (-0.60, -0.16)]
Week 8		122 41.9 (19.17)			243 32.7 (16.17)		
Week 8 chg		122 -26.8 (17.76)	-25.99 (1.53)		243 -34.2 (16.42)	-34.13 (1.08)	-8.15 (-11.8, -4.47) <.001 [-0.48 (-0.70, -0.26)]
Week 10		118 40.4 (20.53)			236 30.2 (16.85)		
Week 10 chg		118 -28.0 (19.22)	-27.39 (1.54)		236 -36.5 (18.20)	-36.38 (1.09)	-8.99 (-12.7, -5.29) <.001 [-0.48 (-0.71, -0.26)]
Week 12		119 39.6 (21.65)			238 29.4 (17.23)		
Week 12 chg		119 -28.8 (20.95)	-28.05 (1.53)		238 -37.6 (18.51)	-37.68 (1.08)	-9.63 (-13.3, -5.94) <.001 [-0.50 (-0.72, -0.27)]

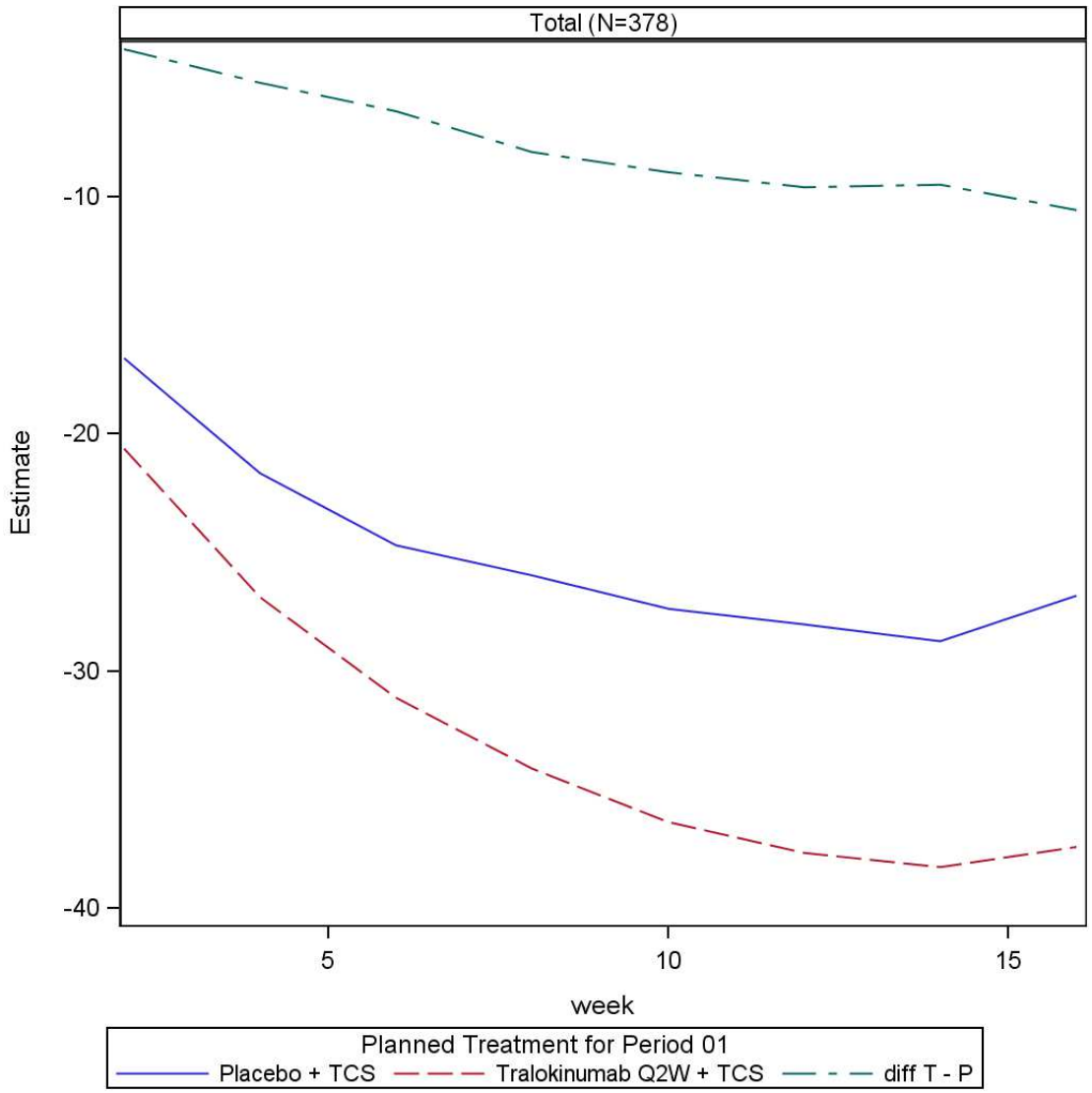
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after 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 1.1.297.3.1: Total, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		118 38.8 (22.39)			235 28.5 (18.20)		
Week 14 chg		118 -29.6 (21.97)	-28.76 (1.54)		235 -38.4 (18.95)	-38.28 (1.09)	-9.52 (-13.2, -5.82) <.001 [-0.48 (-0.70, -0.25)]
Week 16		122 40.9 (23.52)			241 29.4 (18.62)		
Week 16 chg		122 -27.7 (22.50)	-26.84 (1.53)		241 -37.4 (19.31)	-37.43 (1.08)	-10.59 (-14.3, -6.91) <.001 [-0.52 (-0.74, -0.30)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 1.1.297.3.2: Total, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16



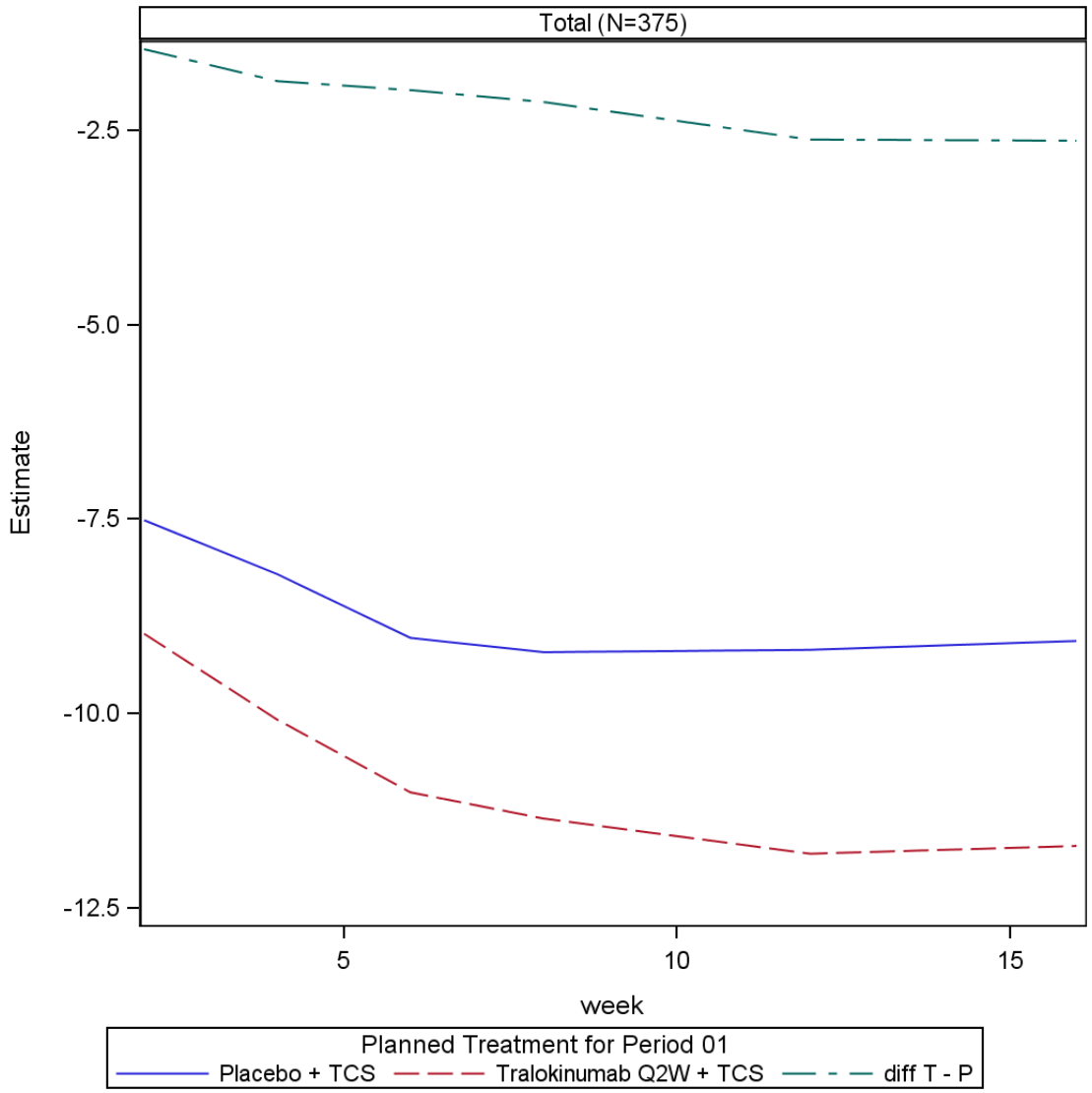
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in SCORAD = Treatment*Week + [Baseline SCORAD]*Week + Region + Baseline IGA. In case of no post-baseline 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 1.1.299.3.1: Total, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	126	125 17.2 (7.15)		252	250 17.6 (7.07)		
Week 2		121 9.8 (7.21)			249 8.6 (6.22)		
Week 2 chg		121 -7.3 (6.72)	-7.51 (0.53)		249 -9.0 (7.25)	-8.97 (0.37)	-1.46 (-2.73, -0.19) 0.024 [-0.21 (-0.42, 0.01)]
Week 4		122 9.1 (7.39)			245 7.4 (6.28)		
Week 4 chg		122 -8.1 (7.14)	-8.21 (0.53)		245 -10.2 (7.54)	-10.08 (0.37)	-1.87 (-3.14, -0.60) 0.004 [-0.25 (-0.47, -0.03)]
Week 6		123 8.4 (6.88)			242 6.3 (5.75)		
Week 6 chg		123 -8.8 (6.70)	-9.03 (0.53)		242 -11.3 (7.41)	-11.01 (0.37)	-1.99 (-3.25, -0.72) 0.002 [-0.28 (-0.49, -0.06)]
Week 8		120 8.1 (6.80)			239 6.2 (5.71)		
Week 8 chg		120 -9.1 (7.09)	-9.21 (0.53)		239 -11.6 (7.90)	-11.35 (0.37)	-2.14 (-3.41, -0.87) 0.001 [-0.28 (-0.50, -0.06)]
Week 12		116 7.9 (7.06)			227 5.7 (5.50)		
Week 12 chg		116 -9.0 (7.22)	-9.18 (0.53)		227 -11.9 (7.98)	-11.80 (0.38)	-2.62 (-3.90, -1.34) <.001 [-0.34 (-0.56, -0.11)]
Week 16		119 8.4 (7.30)			237 5.7 (6.02)		
Week 16 chg		119 -8.8 (7.09)	-9.07 (0.53)		237 -11.8 (7.57)	-11.70 (0.38)	-2.64 (-3.91, -1.36) <.001 [-0.36 (-0.58, -0.13)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 1.1.299.3.2: Total, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16



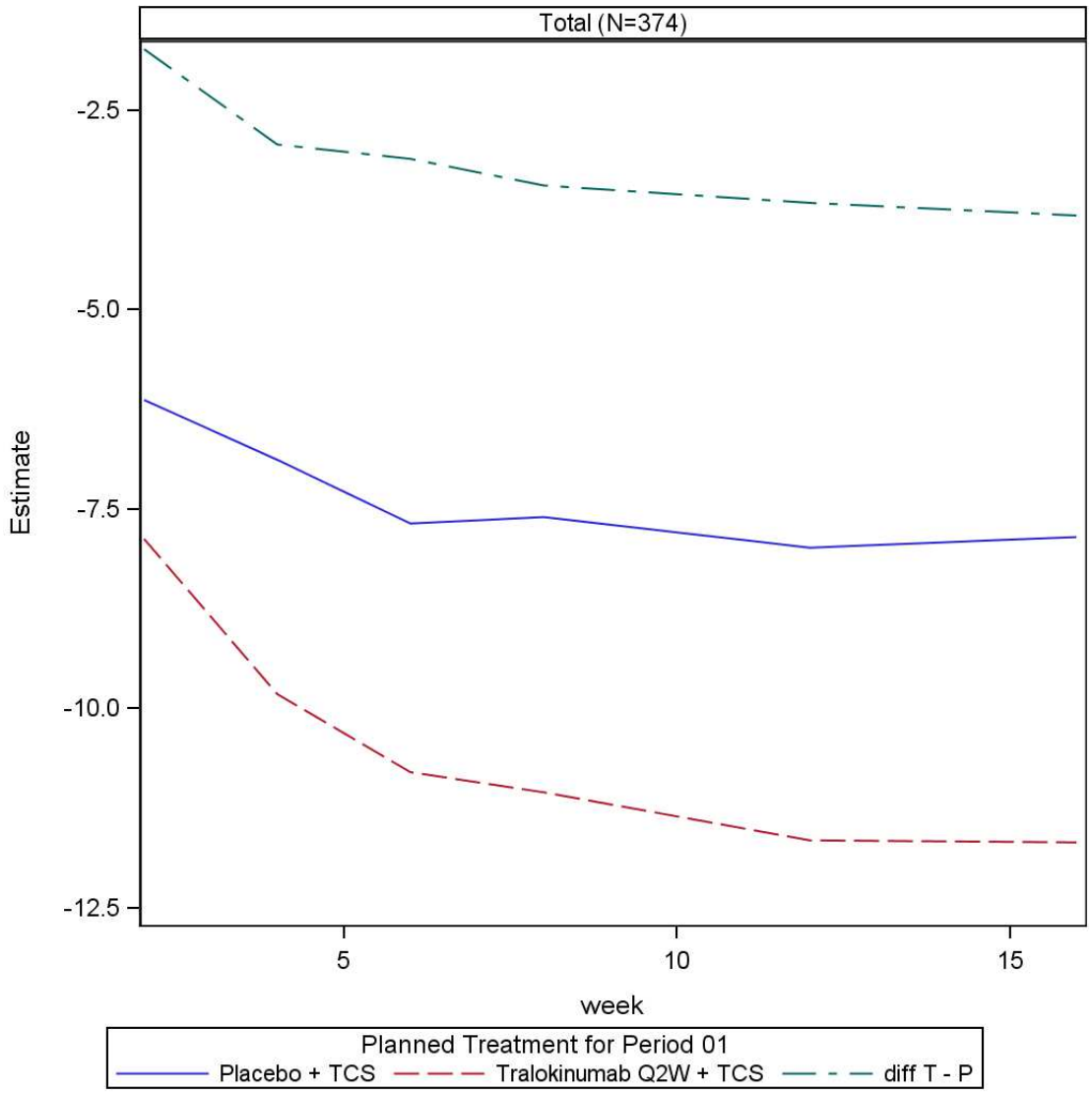
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in DLQI = Treatment*Week + [Baseline DLQI]*Week + Region + Baseline IGA. In case of no post-baseline assessments 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 1.1.300.3.1: Total, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total									
Total									
Baseline	126	124	22.4 (5.63)		252	250	22.3 (5.09)		
Week 2		120	16.2 (7.55)			248	14.4 (6.85)		
Week 2 chg		120	-6.1 (6.67)	-6.14 (0.61)		248	-7.8 (6.57)	-7.88 (0.42)	-1.74 (-3.19, -0.29) 0.019 [-0.26 (-0.48, -0.04)]
Week 4		121	15.5 (7.82)			244	12.5 (6.95)		
Week 4 chg		121	-6.8 (7.00)	-6.89 (0.60)		244	-9.8 (7.02)	-9.82 (0.43)	-2.94 (-4.39, -1.48) <.001 [-0.42 (-0.64, -0.20)]
Week 6		122	14.7 (7.89)			242	11.4 (6.75)		
Week 6 chg		122	-7.7 (7.44)	-7.68 (0.60)		242	-10.9 (6.87)	-10.80 (0.43)	-3.12 (-4.57, -1.66) <.001 [-0.44 (-0.66, -0.22)]
Week 8		119	14.6 (7.88)			239	11.2 (7.08)		
Week 8 chg		119	-7.7 (7.38)	-7.60 (0.61)		239	-11.1 (7.24)	-11.05 (0.43)	-3.45 (-4.91, -1.99) <.001 [-0.47 (-0.70, -0.25)]
Week 12		115	14.0 (8.12)			227	10.6 (6.62)		
Week 12 chg		115	-8.2 (7.71)	-7.99 (0.61)		227	-11.6 (6.72)	-11.65 (0.43)	-3.67 (-5.14, -2.20) <.001 [-0.52 (-0.75, -0.29)]
Week 16		118	14.7 (8.27)			237	10.5 (7.20)		
Week 16 chg		118	-7.8 (7.40)	-7.85 (0.61)		237	-11.7 (7.37)	-11.68 (0.43)	-3.83 (-5.28, -2.37) <.001 [-0.52 (-0.74, -0.29)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 1.1.300.3.2: Total, change in POEM, Treatment policy estimand, LP0162-1339, 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 1.1.318.3.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	126	126 6.9 (2.72)		252	252 6.5 (2.77)		
Week 2		124 4.4 (3.05)			250 3.7 (2.95)		
Week 2 chg		124 -2.5 (2.93)	-2.39 (0.24)		250 -2.8 (2.95)	-2.85 (0.17)	-0.46 (-1.03, 0.11) 0.115 [-0.16 (-0.37, 0.06)]
Week 4		126 3.7 (3.07)			246 3.1 (2.84)		
Week 4 chg		126 -3.1 (3.14)	-2.96 (0.24)		246 -3.3 (3.01)	-3.36 (0.17)	-0.40 (-0.97, 0.17) 0.167 [-0.13 (-0.35, 0.08)]
Week 6		125 3.4 (2.99)			247 2.7 (2.75)		
Week 6 chg		125 -3.5 (3.05)	-3.31 (0.24)		247 -3.7 (3.04)	-3.71 (0.17)	-0.40 (-0.97, 0.17) 0.166 [-0.13 (-0.35, 0.08)]
Week 8		122 3.4 (3.15)			243 2.5 (2.71)		
Week 8 chg		122 -3.4 (3.28)	-3.26 (0.24)		243 -3.9 (2.98)	-3.97 (0.17)	-0.71 (-1.28, -0.14) 0.015 [-0.23 (-0.45, -0.01)]
Week 10		118 3.2 (2.97)			236 2.3 (2.60)		
Week 10 chg		118 -3.6 (3.11)	-3.48 (0.24)		236 -4.1 (3.15)	-4.17 (0.17)	-0.70 (-1.27, -0.12) 0.017 [-0.22 (-0.44, -0.00)]
Week 12		119 3.1 (3.11)			238 2.2 (2.57)		
Week 12 chg		119 -3.7 (3.14)	-3.54 (0.24)		238 -4.2 (3.15)	-4.25 (0.17)	-0.71 (-1.29, -0.14) 0.015 [-0.23 (-0.45, -0.01)]

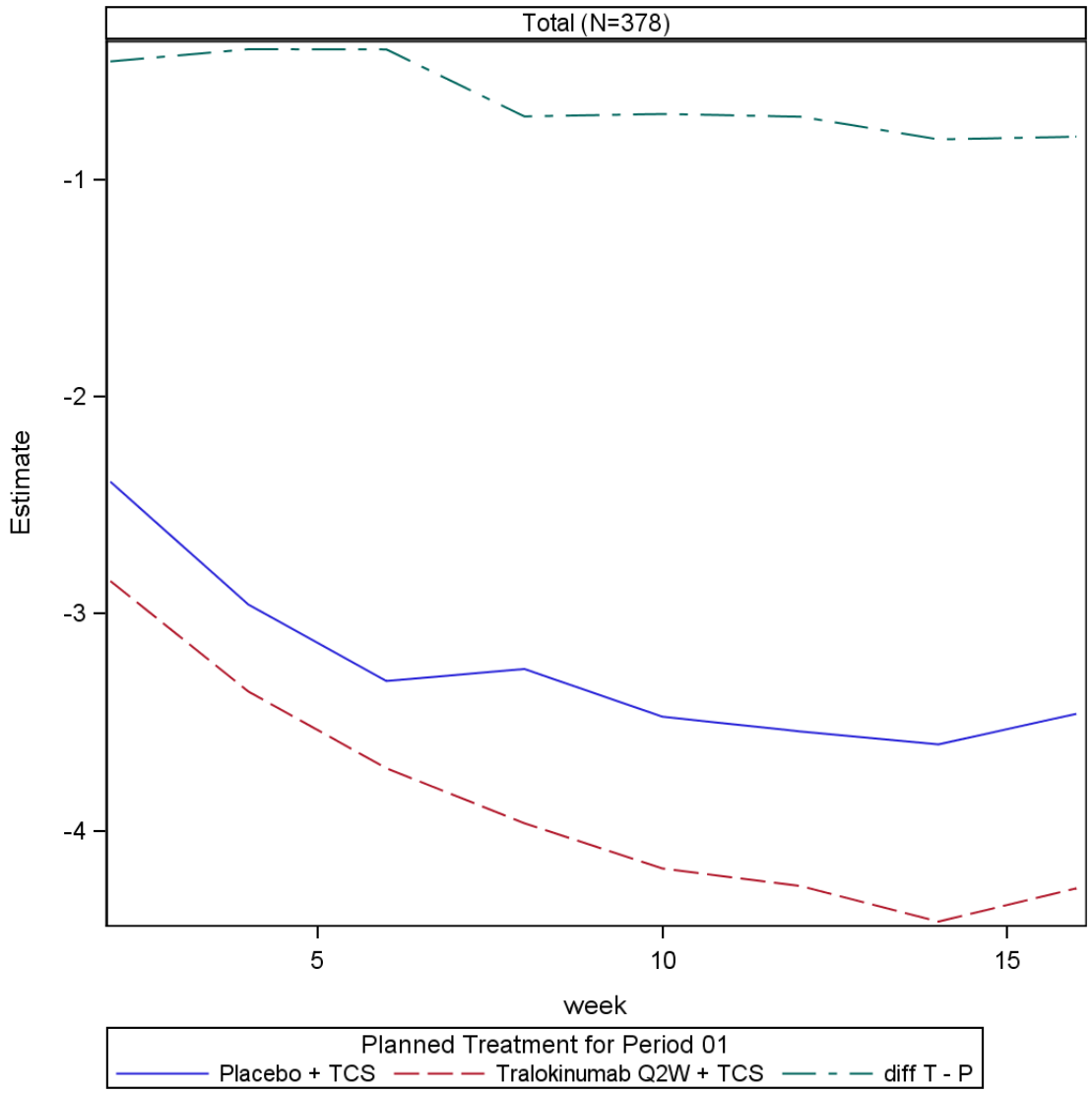
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*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 1.1.318.3.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	3.0 (3.03)		235	2.0 (2.52)			
Week 14 chg	118	-3.8 (3.10)	-3.60 (0.24)	235	-4.4 (3.19)	-4.42 (0.17)	-0.82 (-1.39, -0.24) [-0.26 (-0.48, -0.04)]	0.005
Week 16	122	3.2 (3.24)		241	2.2 (2.68)			
Week 16 chg	122	-3.7 (3.20)	-3.46 (0.24)	241	-4.2 (3.34)	-4.27 (0.17)	-0.80 (-1.38, -0.23) [-0.24 (-0.46, -0.03)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 VAS = Treatment*Week + [Baseline VAS]*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 1.1.318.3.2: Total, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16



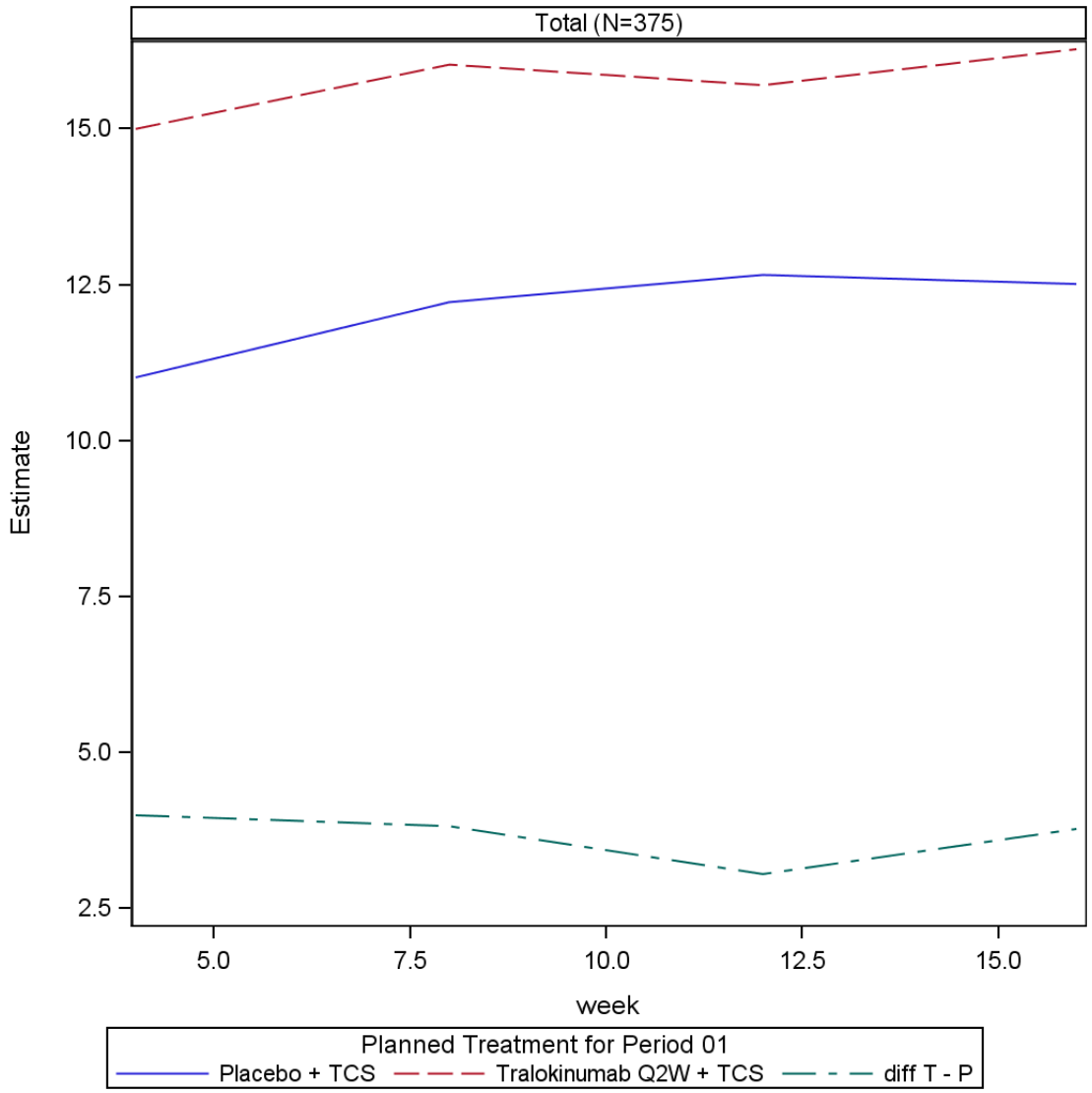
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Region + Baseline IGA. In case of no post-baseline assessments 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 1.1.319.3.1: Total, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	126	125	59.4 (23.09)		252	250	59.1 (25.01)		
Week 4		122	70.1 (18.94)			249	74.1 (18.34)		
Week 4 chg		122	10.3 (18.72)	11.01 (1.54)		249	15.0 (21.76)	15.00 (1.09)	3.99 (0.28, 7.69) 0.035 [0.19 (-0.03, 0.41)]
Week 8		120	71.2 (20.22)			237	75.5 (18.26)		
Week 8 chg		120	12.1 (23.42)	12.22 (1.55)		237	16.4 (23.73)	16.03 (1.10)	3.81 (0.07, 7.55) 0.046 [0.16 (-0.06, 0.38)]
Week 12		116	72.3 (21.36)			227	75.1 (18.28)		
Week 12 chg		116	12.1 (23.53)	12.65 (1.57)		227	16.4 (23.72)	15.70 (1.12)	3.04 (-0.74, 6.83) 0.115 [0.13 (-0.10, 0.35)]
Week 16		116	71.5 (21.22)			232	75.8 (18.84)		
Week 16 chg		116	12.4 (22.66)	12.51 (1.57)		232	17.0 (24.19)	16.27 (1.11)	3.77 (-0.01, 7.55) 0.051 [0.16 (-0.06, 0.38)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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 VAS = Treatment*Week + [Baseline VAS]*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 1.1.319.3.2: Total, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 1.1.322.4.1: Total, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.55 (0.87)		138 -12.9 (10.72)	-13.29 (0.86)	-0.73 (-3.15, 1.68) 0.550 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.46 (0.82)		137 -18.8 (10.58)	-19.37 (0.82)	-1.91 (-4.20, 0.38) 0.102 [-0.17 (-0.41, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.39 (0.85)		134 -20.9 (11.93)	-21.42 (0.85)	-3.03 (-5.40, -0.66) 0.012 [-0.25 (-0.49, -0.01)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.17 (0.86)		130 -22.5 (12.16)	-23.01 (0.86)	-3.83 (-6.23, -1.44) 0.002 [-0.29 (-0.54, -0.05)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.54 (0.78)		130 -24.3 (11.55)	-24.97 (0.78)	-4.44 (-6.62, -2.25) <.001 [-0.35 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-21.04 (0.79)		128 -24.7 (12.40)	-25.12 (0.79)	-4.07 (-6.28, -1.86) <.001 [-0.30 (-0.55, -0.06)]

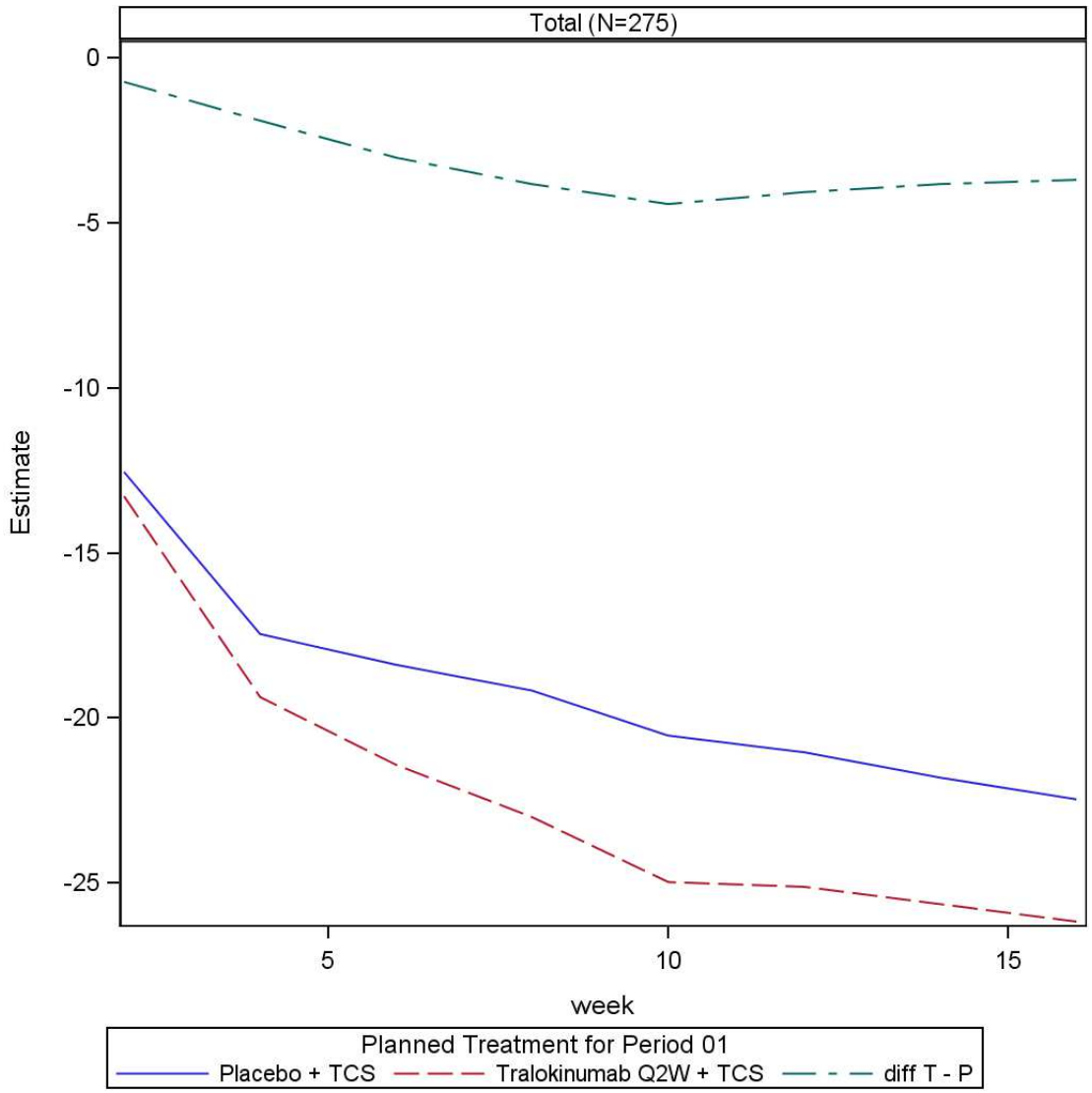
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.322.4.1: Total, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	11.2 (11.57)		127	7.0 (8.34)		
Week 14 chg	126	-22.8 (14.69)	-21.81 (0.85)	127	-25.1 (13.29)	-25.64 (0.85)	-3.83 (-6.20, -1.46) 0.002 [-0.27 (-0.52, -0.03)]
Week 16	124	10.5 (11.42)		123	6.4 (7.63)		
Week 16 chg	124	-23.8 (14.93)	-22.47 (0.83)	123	-25.9 (12.78)	-26.17 (0.83)	-3.70 (-6.02, -1.38) 0.002 [-0.27 (-0.52, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.322.4.2: Total, change in EASI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.325.4.1: Total, EASI 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	88 (63.8)	15.3 (3.72;26.79)	1.3 (1.06; 1.62)	1.9 (1.16; 3.05)	0.0104	
Placebo + TCS	137	67 (48.9)					

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 Prior CSA use and baseline IGA.

04FEB21 22:00 LP0162-Payer /p_bin_eff1/T_t_total_f25_46_w16.txt

Table 1.1.326.4.1: Total, EASI 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	57 (41.3)	14.2 (3.21;25.12)	1.5 (1.09; 2.10)	1.9 (1.15; 3.21)	0.0123	
Placebo + TCS	137	38 (27.7)					

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 Prior CSA use and baseline IGA.

04FEB21 21:44 LP0162-Payer /p_bin_eff1/T_t_total_f26_46_w16.txt

Table 1.1.329.4.1: Total, SCORAD 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	40 (29.0)	16.9 (7.55;26.16)	2.4 (1.42; 3.96)	3.0 (1.58; 5.62)	0.0006	
Placebo + TCS	137	17 (12.4)					

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 Prior CSA use and baseline IGA.

04FEB21 19:31 LP0162-Payer /p_bin_eff1/T_t_total_f29_46_w16.txt

Table 1.1.330.4.1: Total, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	134	62 (46.3)	9.7 (-1.99;21.41)	1.3 (0.95; 1.69)	1.5 (0.92; 2.44)	0.1068	
Placebo + TCS	135	49 (36.3)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

Table 1.1.331.4.1: Total, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	137	85 (62.0)	11.3 (-0.46;23.02)	1.2 (0.99; 1.51)	1.6 (0.98; 2.55)	0.0614	
Placebo + TCS	136	69 (50.7)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 3.

04FEB21 22:53 LP0162-Payer /p_bin_eff1/T_t_total_f31_46_w16.txt

Table 1.1.333.4.1: Total, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	135	105 (77.8)	18.9 (8.08;29.81)	1.3 (1.12; 1.56)	2.5 (1.44; 4.20)	0.0009	
Placebo + TCS	134	79 (59.0)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

04FEB21 19:52 LP0162-Payer /p_bin_eff1/T_t_total_f33_46_w16.txt

Table 1.1.335.4.1: Total, DLQI 0/1, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	32 (23.2)	6.9 (-2.56;16.32)	1.4 (0.87; 2.35)	1.5 (0.85; 2.81)	0.1545	
Placebo + TCS	136	22 (16.2)					

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 Prior CSA use and baseline IGA.

Table 1.1.336.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)									
Total									
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)		
Week 1		135	6.3 (1.69)			136	6.0 (1.78)		
Week 1 chg		135	-1.1 (1.34)	-1.13 (0.11)		136	-1.2 (1.31)	-1.24 (0.11)	-0.10 (-0.42, 0.21) 0.507 [-0.08 (-0.32, 0.16)]
Week 2		134	5.8 (1.97)			132	5.4 (2.11)		
Week 2 chg		134	-1.7 (1.78)	-1.66 (0.15)		132	-1.9 (1.67)	-1.91 (0.15)	-0.25 (-0.65, 0.16) 0.231 [-0.14 (-0.38, 0.10)]
Week 3		133	5.3 (2.17)			131	4.8 (2.08)		
Week 3 chg		133	-2.2 (2.12)	-2.10 (0.17)		131	-2.5 (1.84)	-2.53 (0.17)	-0.43 (-0.89, 0.03) 0.066 [-0.22 (-0.46, 0.02)]
Week 4		130	5.1 (2.25)			133	4.4 (2.14)		
Week 4 chg		130	-2.4 (2.14)	-2.28 (0.17)		133	-2.8 (1.92)	-2.86 (0.17)	-0.59 (-1.06, -0.11) 0.017 [-0.29 (-0.53, -0.05)]
Week 5		131	4.9 (2.37)			129	4.2 (2.15)		
Week 5 chg		131	-2.6 (2.26)	-2.52 (0.18)		129	-3.1 (1.92)	-3.16 (0.18)	-0.64 (-1.14, -0.15) 0.011 [-0.31 (-0.55, -0.06)]
Week 6		130	4.8 (2.35)			129	4.2 (2.16)		
Week 6 chg		130	-2.7 (2.25)	-2.58 (0.18)		129	-3.1 (1.99)	-3.15 (0.18)	-0.57 (-1.07, -0.07) 0.026 [-0.27 (-0.51, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.336.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	4.7 (2.24)		128	4.0 (2.13)			
Week 7 chg	129	-2.8 (2.25)	-2.72 (0.18)	128	-3.3 (2.05)	-3.37 (0.18)	-0.65 (-1.15, -0.16) [-0.30 (-0.55, -0.06)]	0.010
Week 8	127	4.7 (2.32)		125	3.7 (2.10)			
Week 8 chg	127	-2.8 (2.27)	-2.73 (0.18)	125	-3.7 (1.96)	-3.63 (0.18)	-0.89 (-1.39, -0.40) [-0.42 (-0.67, -0.17)]	<.001
Week 9	127	4.6 (2.37)		127	3.6 (2.10)			
Week 9 chg	127	-2.9 (2.32)	-2.79 (0.18)	127	-3.7 (2.03)	-3.70 (0.18)	-0.91 (-1.42, -0.40) [-0.42 (-0.67, -0.17)]	<.001
Week 10	125	4.5 (2.42)		122	3.6 (2.11)			
Week 10 chg	125	-2.9 (2.39)	-2.86 (0.18)	122	-3.7 (1.93)	-3.71 (0.18)	-0.85 (-1.36, -0.34) [-0.39 (-0.64, -0.14)]	0.001
Week 11	128	4.4 (2.41)		126	3.5 (2.15)			
Week 11 chg	128	-3.1 (2.40)	-3.05 (0.18)	126	-3.7 (1.97)	-3.76 (0.18)	-0.71 (-1.22, -0.19) [-0.32 (-0.57, -0.07)]	0.007
Week 12	123	4.4 (2.36)		121	3.5 (2.08)			
Week 12 chg	123	-3.1 (2.41)	-3.01 (0.18)	121	-3.8 (2.06)	-3.82 (0.18)	-0.81 (-1.32, -0.29) [-0.36 (-0.61, -0.11)]	0.002
Week 13	116	4.3 (2.38)		120	3.3 (2.06)			
Week 13 chg	116	-3.3 (2.35)	-3.06 (0.19)	120	-4.0 (2.09)	-3.88 (0.19)	-0.82 (-1.34, -0.30) [-0.37 (-0.63, -0.11)]	0.002

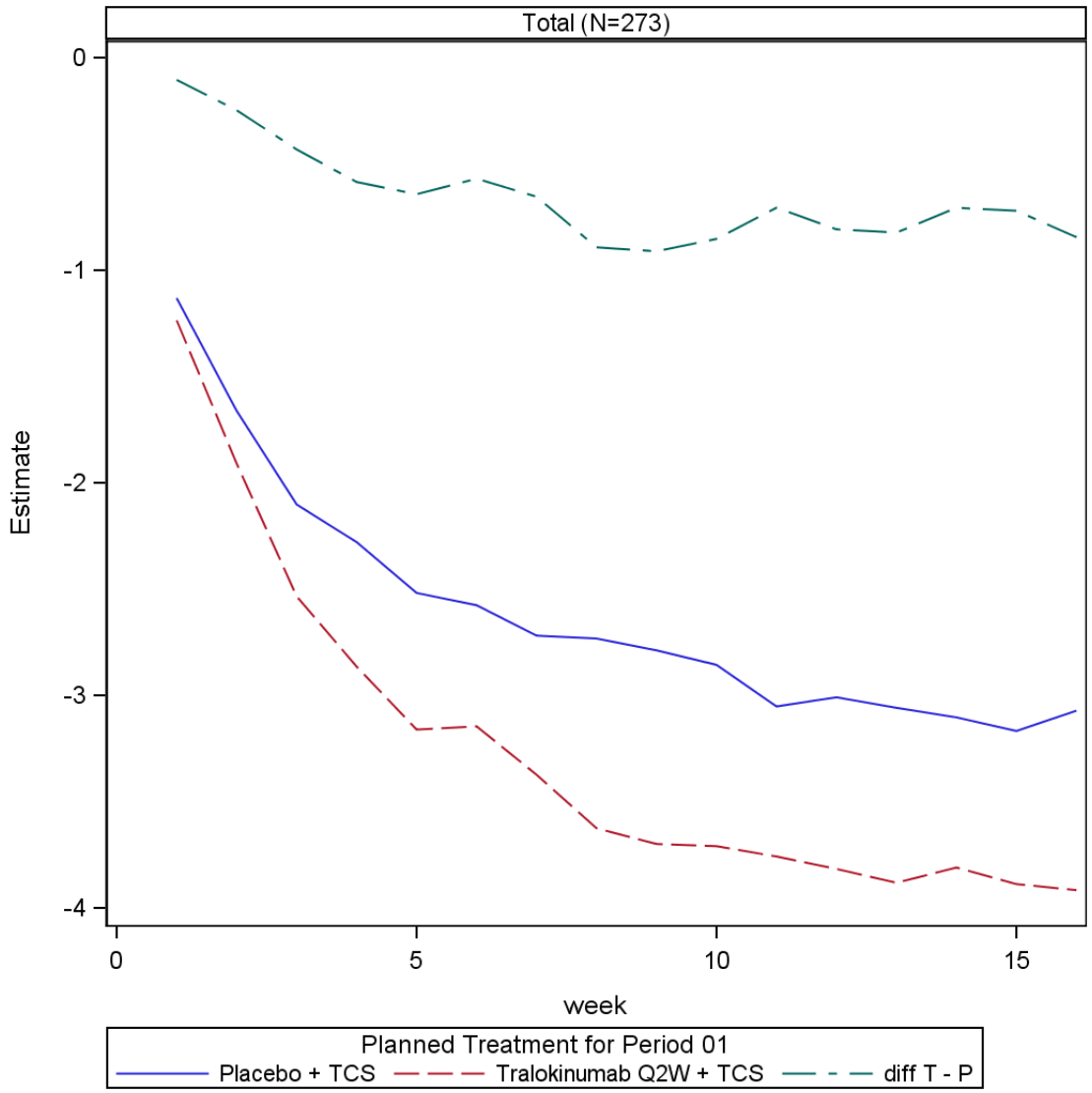
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.336.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.10 (0.19)	123	-3.9 (2.12)	-3.81 (0.19)	-0.71 (-1.24, -0.17) [-0.32 (-0.57, -0.07)]	0.009
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.17 (0.19)	123	-4.0 (2.15)	-3.89 (0.19)	-0.72 (-1.24, -0.20) [-0.32 (-0.57, -0.07)]	0.006
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.07 (0.18)	122	-3.9 (2.06)	-3.92 (0.18)	-0.84 (-1.36, -0.33) [-0.38 (-0.64, -0.13)]	0.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.336.4.2: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.338.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 1		135 5.8 (2.01)			136 5.2 (2.21)		
Week 1 chg		135 -1.1 (1.50)	-1.06 (0.12)		136 -1.1 (1.45)	-1.15 (0.12)	-0.09 (-0.44, 0.26) 0.605 [-0.06 (-0.30, 0.18)]
Week 2		134 5.2 (2.29)			132 4.5 (2.45)		
Week 2 chg		134 -1.7 (1.98)	-1.66 (0.16)		132 -1.8 (1.80)	-1.86 (0.16)	-0.20 (-0.65, 0.25) 0.383 [-0.11 (-0.35, 0.13)]
Week 3		133 4.7 (2.36)			131 3.9 (2.35)		
Week 3 chg		133 -2.2 (2.17)	-2.12 (0.17)		131 -2.4 (2.01)	-2.50 (0.17)	-0.37 (-0.86, 0.11) 0.130 [-0.18 (-0.42, 0.06)]
Week 4		130 4.5 (2.48)			133 3.6 (2.39)		
Week 4 chg		130 -2.4 (2.23)	-2.25 (0.18)		133 -2.7 (2.06)	-2.80 (0.18)	-0.54 (-1.05, -0.04) 0.034 [-0.25 (-0.50, -0.01)]
Week 5		131 4.2 (2.55)			129 3.3 (2.42)		
Week 5 chg		131 -2.7 (2.37)	-2.54 (0.19)		129 -3.0 (2.16)	-3.14 (0.19)	-0.60 (-1.13, -0.07) 0.026 [-0.27 (-0.51, -0.02)]
Week 6		130 4.2 (2.52)			129 3.3 (2.42)		
Week 6 chg		130 -2.7 (2.36)	-2.53 (0.19)		129 -3.1 (2.24)	-3.20 (0.19)	-0.67 (-1.21, -0.14) 0.014 [-0.29 (-0.54, -0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.338.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	129 3.9 (2.43)		128	128 3.1 (2.37)		
Week 7 chg	129	129 -3.0 (2.38)	-2.80 (0.19)	128	128 -3.3 (2.28)	-3.40 (0.19)	-0.60 (-1.13, -0.07) 0.027 [-0.26 (-0.50, -0.01)]
Week 8	127	127 3.9 (2.46)		125	125 2.8 (2.29)		
Week 8 chg	127	127 -3.0 (2.32)	-2.80 (0.19)	125	125 -3.6 (2.26)	-3.63 (0.19)	-0.82 (-1.35, -0.30) 0.002 [-0.36 (-0.61, -0.11)]
Week 9	127	127 3.8 (2.49)		127	127 2.6 (2.22)		
Week 9 chg	127	127 -3.1 (2.33)	-2.92 (0.19)	127	127 -3.7 (2.23)	-3.82 (0.19)	-0.90 (-1.42, -0.38) <.001 [-0.39 (-0.64, -0.14)]
Week 10	125	125 3.7 (2.54)		122	122 2.7 (2.29)		
Week 10 chg	125	125 -3.2 (2.40)	-3.01 (0.19)	122	122 -3.7 (2.29)	-3.80 (0.19)	-0.79 (-1.33, -0.25) 0.004 [-0.34 (-0.59, -0.09)]
Week 11	128	128 3.6 (2.46)		126	126 2.6 (2.22)		
Week 11 chg	128	128 -3.3 (2.40)	-3.15 (0.19)	126	126 -3.8 (2.26)	-3.88 (0.19)	-0.73 (-1.26, -0.20) 0.007 [-0.31 (-0.56, -0.07)]
Week 12	123	123 3.5 (2.44)		121	121 2.5 (2.21)		
Week 12 chg	123	123 -3.4 (2.45)	-3.16 (0.19)	121	121 -3.8 (2.38)	-3.97 (0.19)	-0.81 (-1.34, -0.27) 0.003 [-0.33 (-0.59, -0.08)]
Week 13	116	116 3.4 (2.40)		120	120 2.3 (2.13)		
Week 13 chg	116	116 -3.6 (2.32)	-3.28 (0.18)	120	120 -3.9 (2.26)	-4.01 (0.18)	-0.72 (-1.24, -0.21) 0.006 [-0.31 (-0.57, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

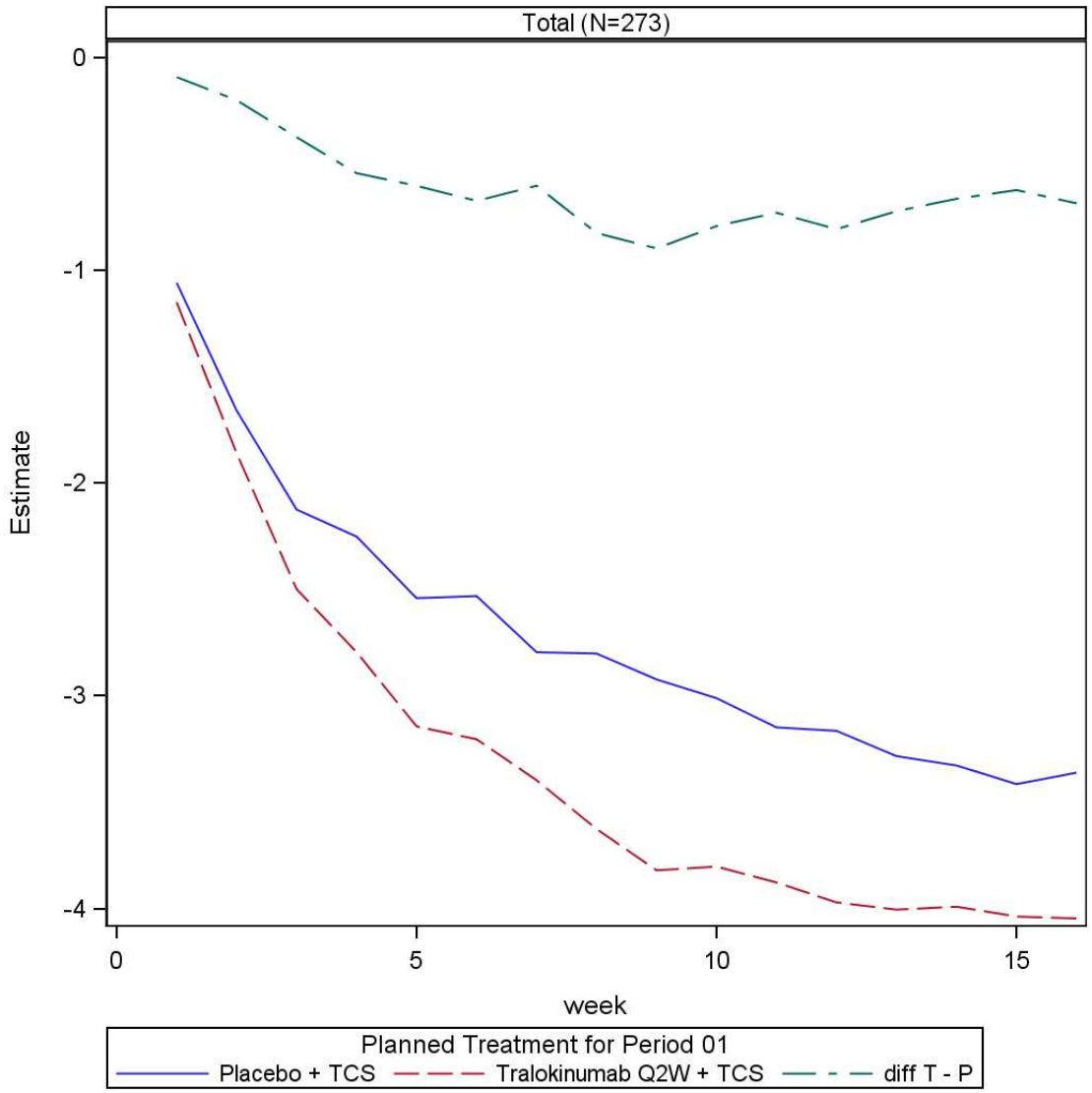
12MAY21 12:36 LP0162-Payer /p_mmrm3/t_t_total_f38_46_w16.txt

Table 1.1.338.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	3.3 (2.42)		123	2.4 (2.18)			
Week 14 chg	123	-3.5 (2.33)	-3.33 (0.19)	123	-3.9 (2.27)	-3.99 (0.19)	-0.66 (-1.19, -0.14) [-0.29 (-0.54, -0.04)]	0.014
Week 15	123	3.3 (2.47)		123	2.4 (2.18)			
Week 15 chg	123	-3.7 (2.35)	-3.42 (0.19)	123	-3.9 (2.35)	-4.04 (0.19)	-0.62 (-1.15, -0.10) [-0.26 (-0.52, -0.01)]	0.021
Week 16	121	3.2 (2.40)		122	2.5 (2.17)			
Week 16 chg	121	-3.7 (2.28)	-3.36 (0.19)	122	-3.9 (2.32)	-4.05 (0.19)	-0.68 (-1.21, -0.16) [-0.30 (-0.55, -0.04)]	0.010

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.338.4.2: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.340.4.1: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.23 (1.35)		138 -20.9 (16.72)	-21.06 (1.35)	-3.83 (-7.59, -0.07) 0.046 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.23 (1.45)		137 -30.8 (17.25)	-30.98 (1.44)	-4.74 (-8.77, -0.71) 0.021 [-0.27 (-0.50, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.72 (1.47)		134 -34.3 (17.49)	-34.44 (1.46)	-7.72 (-11.8, -3.64) <.001 [-0.42 (-0.66, -0.18)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.60 (1.54)		130 -36.6 (18.48)	-36.65 (1.54)	-8.05 (-12.3, -3.77) <.001 [-0.42 (-0.66, -0.17)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.72 (1.60)		130 -38.5 (19.49)	-38.47 (1.60)	-7.75 (-12.2, -3.30) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.57 (1.51)		128 -39.5 (18.74)	-39.42 (1.51)	-7.85 (-12.0, -3.64) <.001 [-0.41 (-0.66, -0.16)]

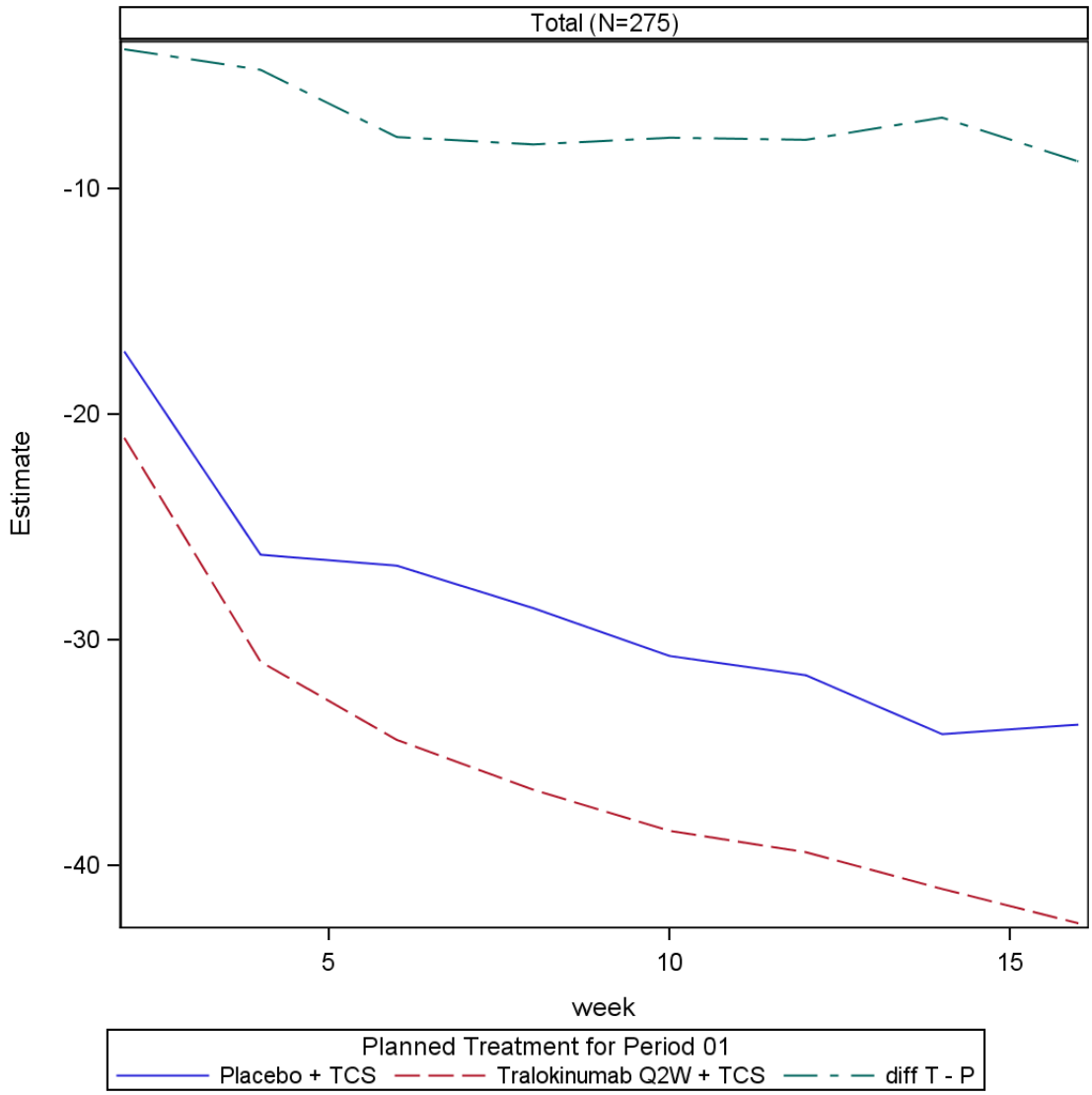
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.340.4.1: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14		126 36.0 (19.61)			127 28.3 (17.87)			
Week 14 chg		126 -34.8 (20.31)	-34.19 (1.62)		127 -41.8 (20.11)	-41.05 (1.62)	-6.86 (-11.4, -2.34) [-0.34 (-0.59, -0.09)]	0.003
Week 16		124 36.3 (18.78)			123 27.0 (16.90)			
Week 16 chg		124 -34.7 (19.94)	-33.76 (1.55)		123 -43.3 (19.46)	-42.57 (1.55)	-8.81 (-13.1, -4.50) [-0.45 (-0.70, -0.19)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.340.4.2: Total, change in SCORAD, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.342.4.1: Total, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score										
Total										
Baseline	137	134	16.4 (6.33)		138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)			132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.16 (0.45)		132	-7.5 (5.92)	-7.53 (0.45)	-0.37 (-1.61, 0.88) [-0.06 (-0.30, 0.18)]	0.562
Week 4		130	7.8 (6.27)			135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.28 (0.48)		135	-9.0 (6.32)	-9.11 (0.47)	-0.83 (-2.16, 0.49) [-0.13 (-0.37, 0.11)]	0.217
Week 6		123	7.3 (6.07)			126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.58 (0.50)		126	-10.0 (6.75)	-9.85 (0.50)	-1.27 (-2.66, 0.12) [-0.18 (-0.43, 0.07)]	0.073
Week 8		127	6.9 (5.70)			128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.96 (0.45)		128	-10.6 (6.29)	-10.32 (0.45)	-1.36 (-2.61, -0.10) [-0.21 (-0.45, 0.04)]	0.034
Week 12		123	6.8 (5.89)			124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.36 (0.42)		124	-10.6 (5.77)	-10.62 (0.42)	-1.26 (-2.43, -0.09) [-0.19 (-0.44, 0.06)]	0.035
Week 16		120	6.5 (5.63)			118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.71 (0.40)		118	-11.0 (5.99)	-11.21 (0.40)	-1.50 (-2.62, -0.39) [-0.24 (-0.49, 0.02)]	0.008

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

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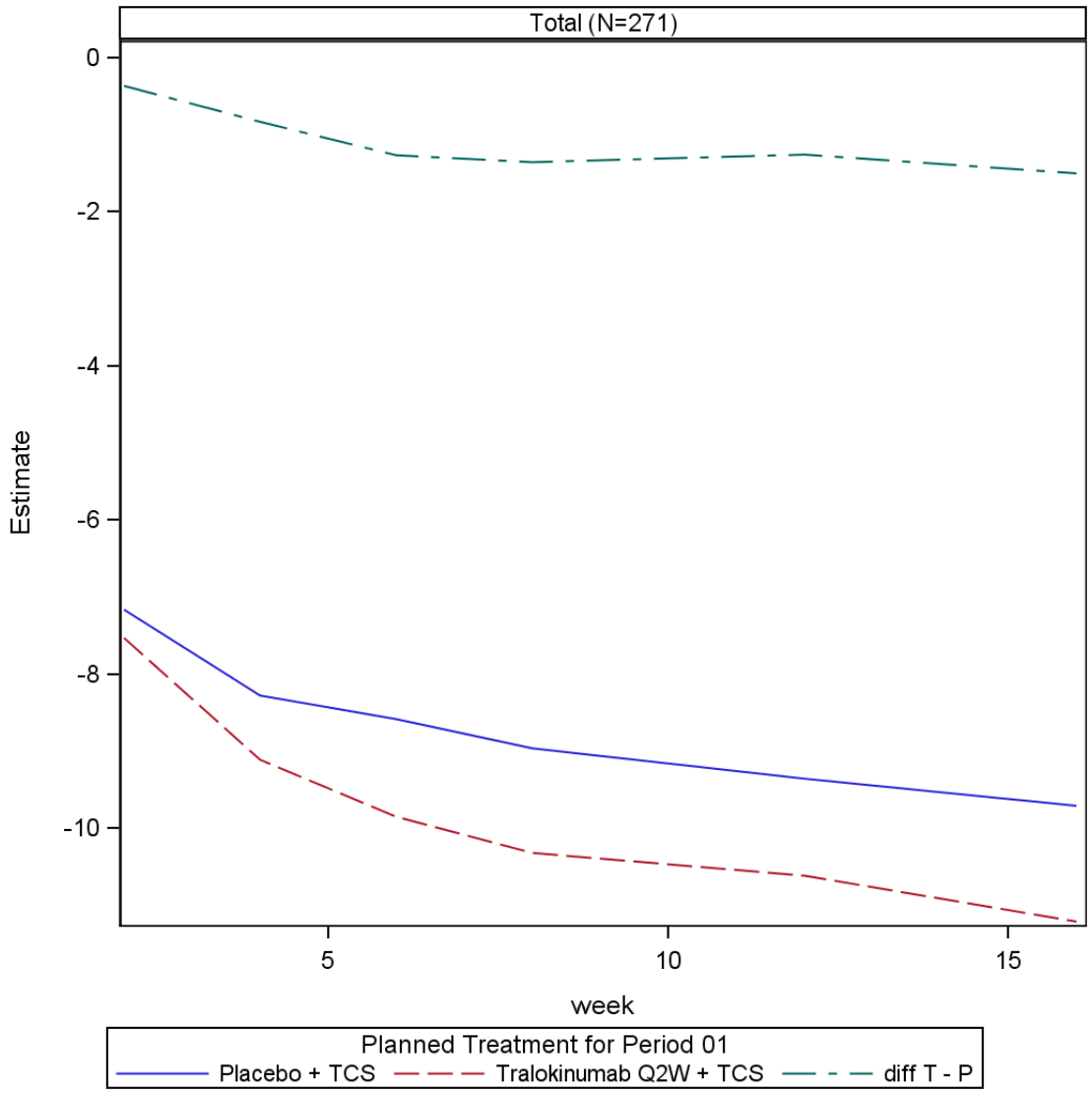
Figure 1.1.342.4.2: Total, change in DLQI, Treatment policy, LP0162-1346, Week 16



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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.343.4.1: Total, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 2		130 15.1 (6.91)			130 13.5 (6.31)			
Week 2 chg		130 -5.9 (6.29)	-6.01 (0.49)		130 -7.7 (5.43)	-7.67 (0.49)	-1.67 (-3.03, -0.31)	0.017
							[-0.28 (-0.53, -0.04)]	
Week 4		130 13.8 (7.45)			133 11.6 (6.30)			
Week 4 chg		130 -7.1 (7.56)	-7.10 (0.55)		133 -9.7 (6.02)	-9.51 (0.55)	-2.41 (-3.94, -0.87)	0.002
							[-0.35 (-0.60, -0.11)]	
Week 6		123 13.5 (7.81)			124 10.9 (5.95)			
Week 6 chg		123 -7.2 (8.29)	-7.33 (0.58)		124 -10.6 (6.27)	-10.36 (0.58)	-3.02 (-4.65, -1.40)	<.001
							[-0.41 (-0.66, -0.16)]	
Week 8		127 13.1 (7.02)			126 9.9 (5.79)			
Week 8 chg		127 -7.6 (7.95)	-7.75 (0.55)		126 -11.5 (6.10)	-11.14 (0.55)	-3.39 (-4.91, -1.86)	<.001
							[-0.48 (-0.73, -0.23)]	
Week 12		123 13.0 (7.39)			122 9.2 (5.72)			
Week 12 chg		123 -8.0 (8.26)	-7.94 (0.57)		122 -12.4 (6.20)	-11.86 (0.57)	-3.92 (-5.50, -2.34)	<.001
							[-0.54 (-0.79, -0.28)]	
Week 16		120 13.0 (7.69)			116 9.1 (5.58)			
Week 16 chg		120 -8.0 (8.09)	-8.05 (0.57)		116 -12.2 (6.39)	-11.89 (0.58)	-3.84 (-5.44, -2.24)	<.001
							[-0.53 (-0.79, -0.27)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

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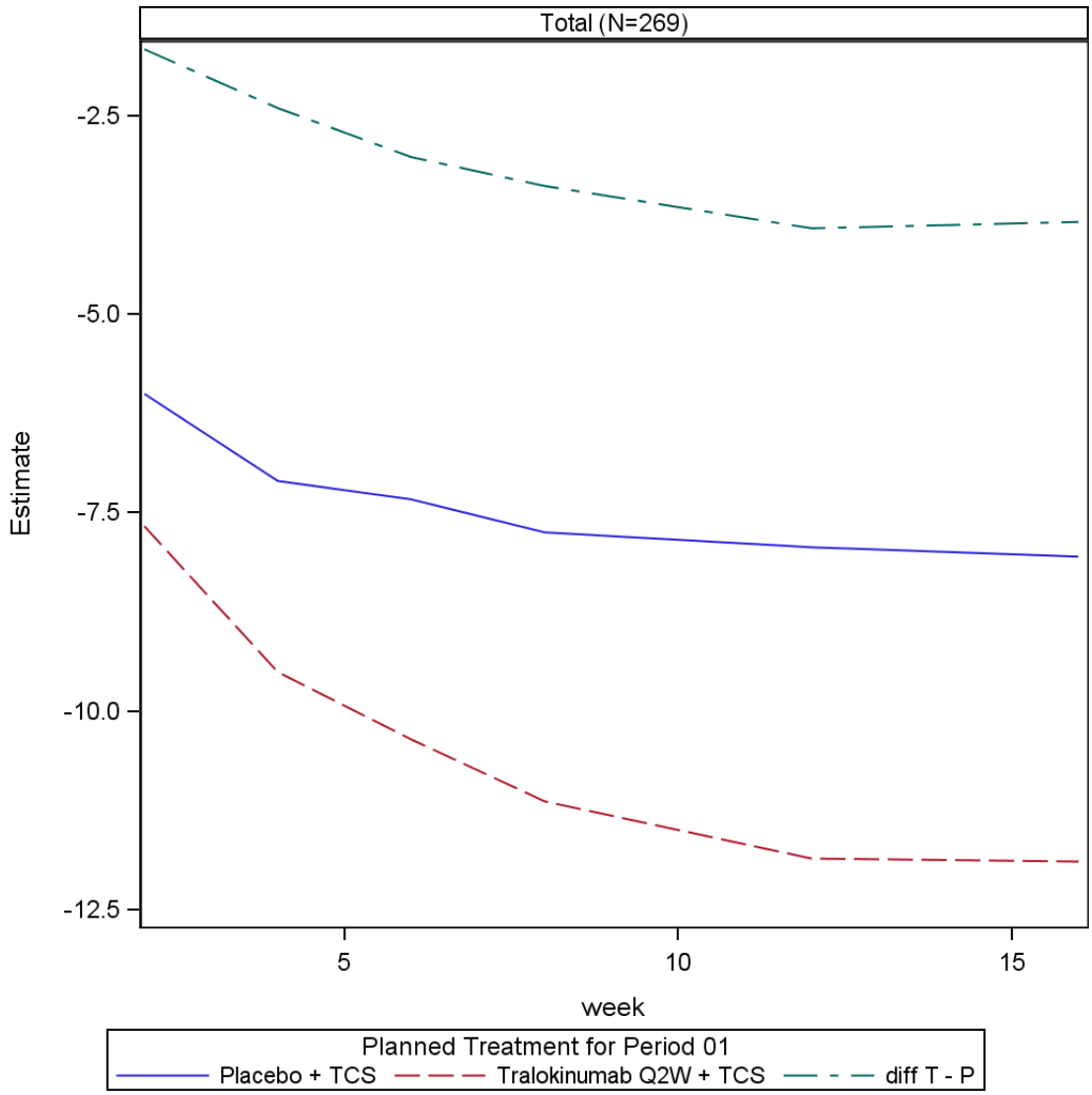
Figure 1.1.343.4.2: Total, change in POEM, Treatment policy, LP0162-1346, Week 16



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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.355.4.1: Total, EASI 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	96 (69.6)	16.8 (5.65;27.89)	1.3 (1.09; 1.59)	2.1 (1.27; 3.49)	0.0039	
Placebo + TCS	137	73 (53.3)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.1.356.4.1: Total, EASI 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	67 (48.6)	14.1 (2.87;25.40)	1.4 (1.06; 1.86)	1.8 (1.12; 3.04)	0.0160	
Placebo + TCS	137	48 (35.0)					

Treatment policy estimand: Missing values at Week 26 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.

04FEB21 23:26 LP0162-Payer /p_bin_eff1/T_t_total_f56_46_w26.txt

Table 1.1.359.4.1: Total, SCORAD 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	53 (38.4)	20.6 (10.39;30.82)	2.1 (1.42; 3.22)	3.0 (1.68; 5.21)	0.0001	
Placebo + TCS	137	25 (18.2)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.1.360.4.1: Total, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	134	64 (47.8)	8.3 (-3.43;20.09)	1.2 (0.92; 1.60)	1.4 (0.87; 2.29)	0.1650	
Placebo + TCS	135	53 (39.3)					

Treatment policy estimand: Missing values at Week 26 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.

04FEB21 22:45 LP0162-Payer /p_bin_eff1/T_t_total_f60_46_w26.txt

Table 1.1.361.4.1: Total, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	137	86 (62.8)	16.0 (4.45;27.60)	1.3 (1.08; 1.67)	1.9 (1.19; 3.16)	0.0078	
Placebo + TCS	136	64 (47.1)					

Treatment policy estimand: Missing values at Week 26 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.

04FEB21 18:56 LP0162-Payer /p_bin_eff1/T_t_total_f61_46_w26.txt

Table 1.1.363.4.1: Total, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	135	105 (77.8)	21.3 (10.39;32.18)	1.4 (1.16; 1.64)	2.7 (1.59; 4.63)	0.0002	
Placebo + TCS	134	76 (56.7)					

Treatment policy estimand: Missing values at Week 26 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.

04FEB21 21:56 LP0162-Payer /p_bin_eff1/T_t_total_f63_46_w26.txt

Table 1.1.365.4.1: Total, DLQI 0/1, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	36 (26.1)	13.7 (4.62;22.81)	2.1 (1.25; 3.56)	2.5 (1.34; 4.85)	0.0038	
Placebo + TCS	136	17 (12.5)					

Treatment policy estimand: Missing values at Week 26 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.

04FEB21 19:43 LP0162-Payer /p_bin_eff1/T_t_total_f65_46_w26.txt

Table 1.1.366.4.1: Total, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.59 (0.87)		138 -12.9 (10.72)	-13.35 (0.87)	-0.76 (-3.17, 1.66) 0.538 [-0.07 (-0.31, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.53 (0.82)		137 -18.8 (10.58)	-19.45 (0.82)	-1.92 (-4.21, 0.36) 0.099 [-0.17 (-0.41, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.48 (0.85)		134 -20.9 (11.93)	-21.52 (0.85)	-3.04 (-5.41, -0.68) 0.012 [-0.25 (-0.49, -0.01)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.26 (0.86)		130 -22.5 (12.16)	-23.12 (0.86)	-3.86 (-6.25, -1.46) 0.002 [-0.30 (-0.54, -0.05)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.64 (0.78)		130 -24.3 (11.55)	-25.09 (0.78)	-4.45 (-6.63, -2.26) <.001 [-0.35 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-21.16 (0.79)		128 -24.7 (12.40)	-25.24 (0.79)	-4.08 (-6.28, -1.88) <.001 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

12MAY21 13:11 LP0162-Payer /p_mmrm3/t_t_total_f66_46_w26.txt

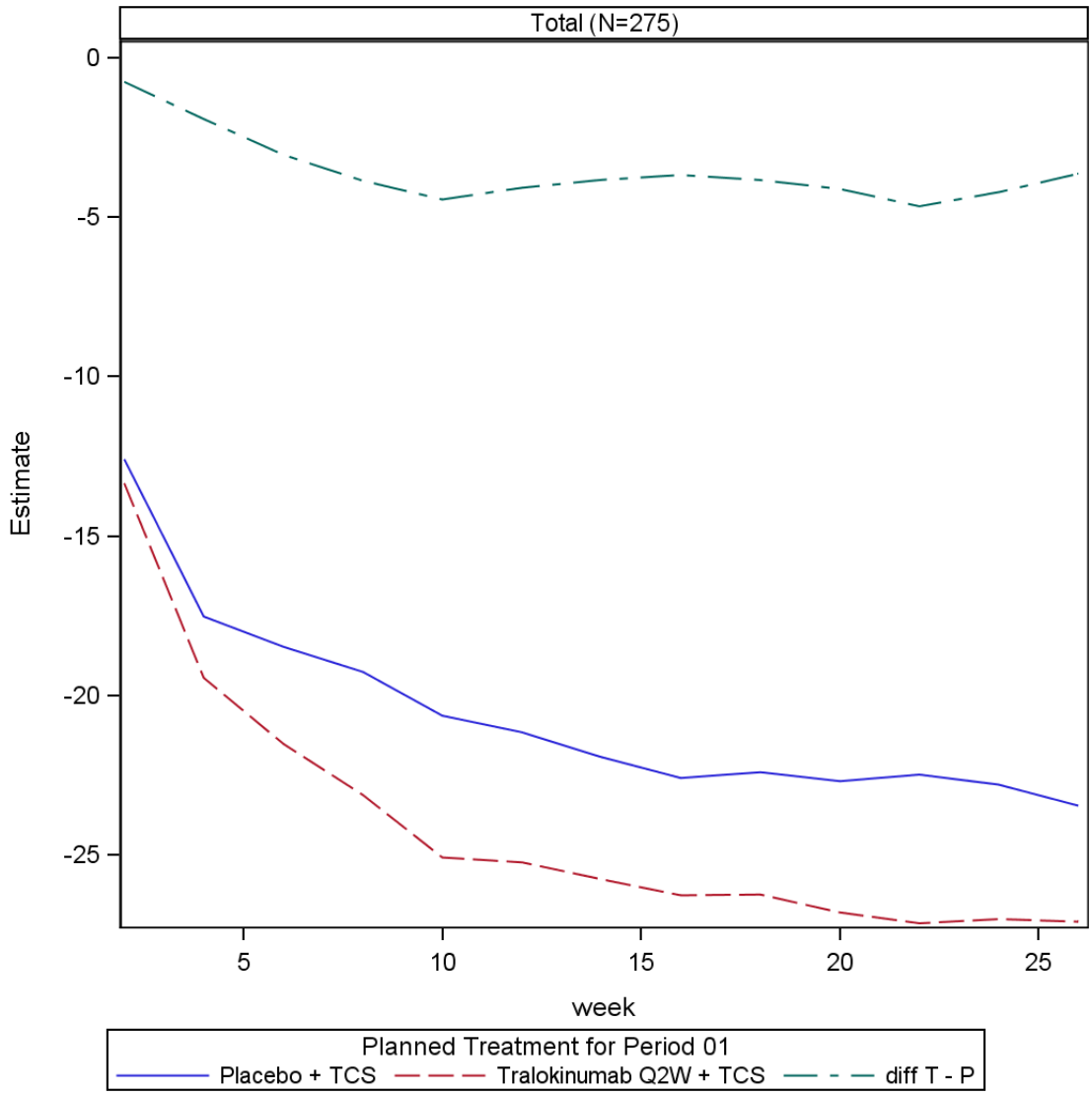
Table 1.1.366.4.1: Total, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 11.2 (11.57)			127 7.0 (8.34)		
Week 14 chg		126 -22.8 (14.69)	-21.94 (0.85)		127 -25.1 (13.29)	-25.77 (0.85)	-3.83 (-6.20, -1.47) 0.002 [-0.27 (-0.52, -0.03)]
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.59 (0.83)		123 -25.9 (12.78)	-26.27 (0.83)	-3.68 (-5.99, -1.37) 0.002 [-0.26 (-0.52, -0.01)]
Week 18		116 10.7 (11.52)			115 5.9 (7.36)		
Week 18 chg		116 -23.6 (14.71)	-22.41 (0.83)		115 -26.4 (12.11)	-26.25 (0.83)	-3.84 (-6.16, -1.52) 0.001 [-0.28 (-0.54, -0.03)]
Week 20		107 10.6 (12.56)			117 5.5 (6.56)		
Week 20 chg		107 -24.1 (15.32)	-22.69 (0.84)		117 -26.9 (11.94)	-26.81 (0.84)	-4.12 (-6.47, -1.77) <.001 [-0.30 (-0.57, -0.04)]
Week 22		112 10.5 (11.17)			114 5.0 (5.93)		
Week 22 chg		112 -24.3 (14.63)	-22.49 (0.81)		114 -27.3 (12.17)	-27.15 (0.81)	-4.66 (-6.92, -2.40) <.001 [-0.35 (-0.61, -0.08)]
Week 24		112 9.9 (11.00)			117 5.3 (7.21)		
Week 24 chg		112 -24.9 (14.38)	-22.80 (0.83)		117 -27.0 (12.11)	-27.02 (0.82)	-4.22 (-6.52, -1.91) <.001 [-0.32 (-0.58, -0.06)]
Week 26		118 9.1 (10.14)			125 5.6 (7.90)		
Week 26 chg		118 -25.5 (13.74)	-23.46 (0.79)		125 -26.5 (12.83)	-27.10 (0.79)	-3.64 (-5.84, -1.43) 0.001 [-0.27 (-0.53, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

12MAY21 13:11 LP0162-Payer /p_mmrm3/t_t_total_f66_46_w26.txt

Figure 1.1.366.4.2: Total, change in EASI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.372.4.1: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.24 (1.35)		138 -20.9 (16.72)	-21.10 (1.35)	-3.86 (-7.63, -0.10) 0.045 [-0.24 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.27 (1.45)		137 -30.8 (17.25)	-31.03 (1.44)	-4.75 (-8.78, -0.72) 0.021 [-0.27 (-0.51, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.77 (1.47)		134 -34.3 (17.49)	-34.50 (1.46)	-7.73 (-11.8, -3.65) <.001 [-0.42 (-0.66, -0.18)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.64 (1.53)		130 -36.6 (18.48)	-36.70 (1.54)	-8.06 (-12.3, -3.78) <.001 [-0.42 (-0.66, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.76 (1.60)		130 -38.5 (19.49)	-38.53 (1.60)	-7.77 (-12.2, -3.32) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.63 (1.51)		128 -39.5 (18.74)	-39.44 (1.51)	-7.81 (-12.0, -3.61) <.001 [-0.41 (-0.65, -0.16)]

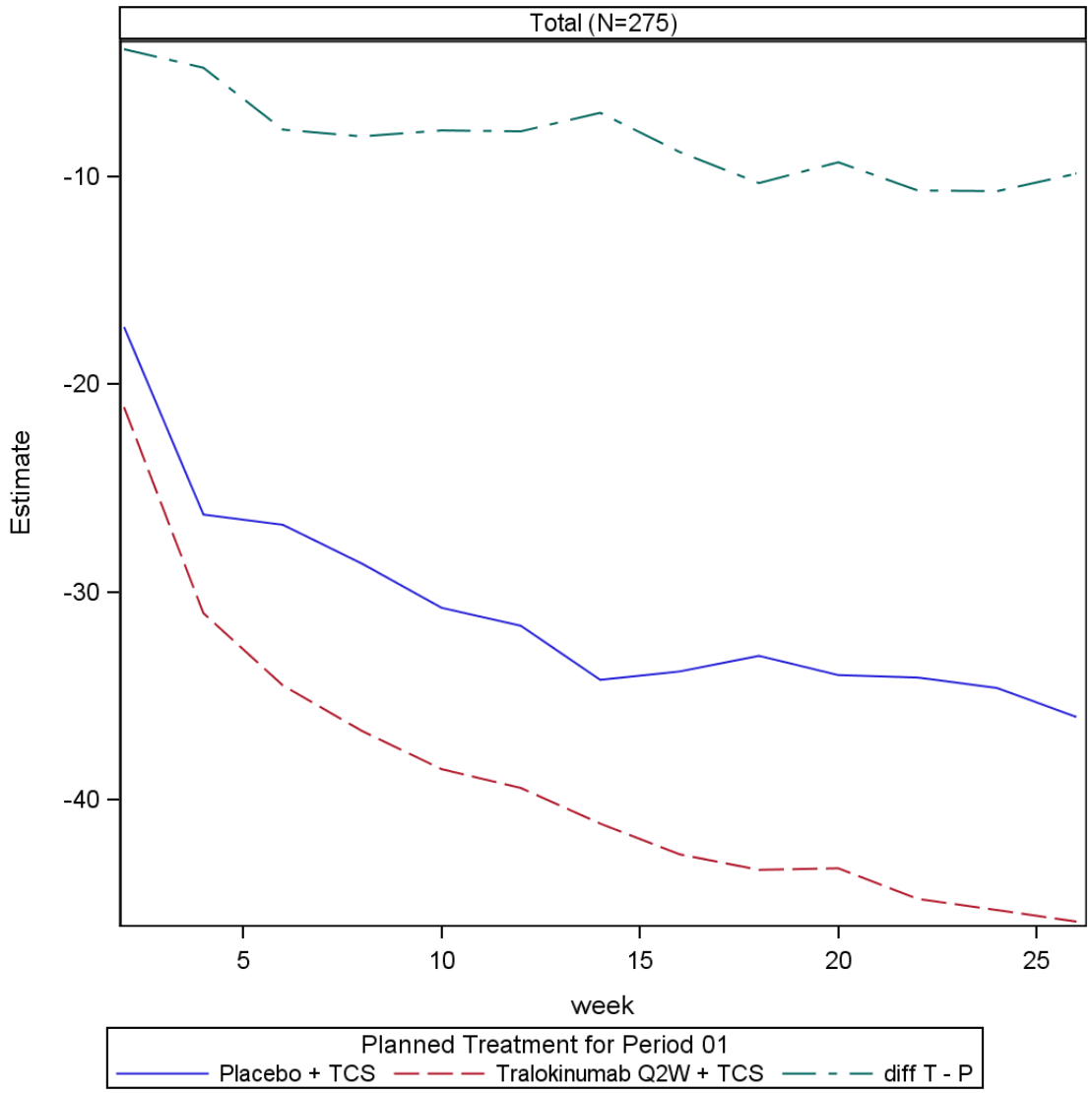
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.372.4.1: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 36.0 (19.61)			127 28.3 (17.87)		
Week 14 chg		126 -34.8 (20.31)	-34.24 (1.62)		127 -41.8 (20.11)	-41.16 (1.61)	-6.92 (-11.4, -2.43) 0.003 [-0.34 (-0.59, -0.09)]
Week 16		124 36.3 (18.78)			123 27.0 (16.90)		
Week 16 chg		124 -34.7 (19.94)	-33.83 (1.54)		123 -43.3 (19.46)	-42.64 (1.54)	-8.81 (-13.1, -4.53) <.001 [-0.45 (-0.70, -0.19)]
Week 18		116 36.8 (19.98)			115 25.1 (15.97)		
Week 18 chg		116 -34.1 (20.70)	-33.08 (1.63)		115 -44.8 (19.27)	-43.39 (1.63)	-10.31 (-14.9, -5.76) <.001 [-0.52 (-0.78, -0.25)]
Week 20		107 35.7 (19.63)			117 25.6 (16.83)		
Week 20 chg		107 -35.6 (20.01)	-34.01 (1.61)		117 -44.9 (18.80)	-43.31 (1.59)	-9.31 (-13.8, -4.84) <.001 [-0.48 (-0.75, -0.21)]
Week 22		112 35.6 (20.27)			114 23.3 (14.77)		
Week 22 chg		112 -35.5 (20.64)	-34.12 (1.64)		114 -46.8 (19.03)	-44.79 (1.63)	-10.67 (-15.2, -6.11) <.001 [-0.54 (-0.80, -0.27)]
Week 24		112 34.6 (19.86)			117 23.3 (15.61)		
Week 24 chg		112 -36.5 (20.30)	-34.63 (1.61)		117 -46.9 (18.55)	-45.32 (1.59)	-10.70 (-15.2, -6.24) <.001 [-0.55 (-0.81, -0.29)]
Week 26		118 33.1 (18.32)			125 23.8 (16.51)		
Week 26 chg		118 -38.1 (19.21)	-36.02 (1.54)		125 -46.3 (19.60)	-45.88 (1.53)	-9.85 (-14.1, -5.58) <.001 [-0.51 (-0.76, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.372.4.2: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.374.4.1: Total, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score											
Total											
Baseline	137	134	16.4 (6.33)			138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)				132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.15 (0.45)			132	-7.5 (5.92)	-7.51 (0.44)		-0.36 (-1.61, 0.88) 0.566 [-0.06 (-0.30, 0.18)]
Week 4		130	7.8 (6.27)				135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.26 (0.48)			135	-9.0 (6.32)	-9.09 (0.47)		-0.83 (-2.16, 0.50) 0.219 [-0.13 (-0.37, 0.11)]
Week 6		123	7.3 (6.07)				126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.55 (0.50)			126	-10.0 (6.75)	-9.83 (0.50)		-1.28 (-2.66, 0.11) 0.072 [-0.18 (-0.43, 0.07)]
Week 8		127	6.9 (5.70)				128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.94 (0.45)			128	-10.6 (6.29)	-10.29 (0.45)		-1.35 (-2.61, -0.09) 0.035 [-0.21 (-0.45, 0.04)]
Week 12		123	6.8 (5.89)				124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.36 (0.42)			124	-10.6 (5.77)	-10.58 (0.42)		-1.22 (-2.39, -0.04) 0.043 [-0.19 (-0.44, 0.06)]
Week 16		120	6.5 (5.63)				118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.70 (0.40)			118	-11.0 (5.99)	-11.14 (0.40)		-1.44 (-2.56, -0.32) 0.012 [-0.23 (-0.48, 0.03)]

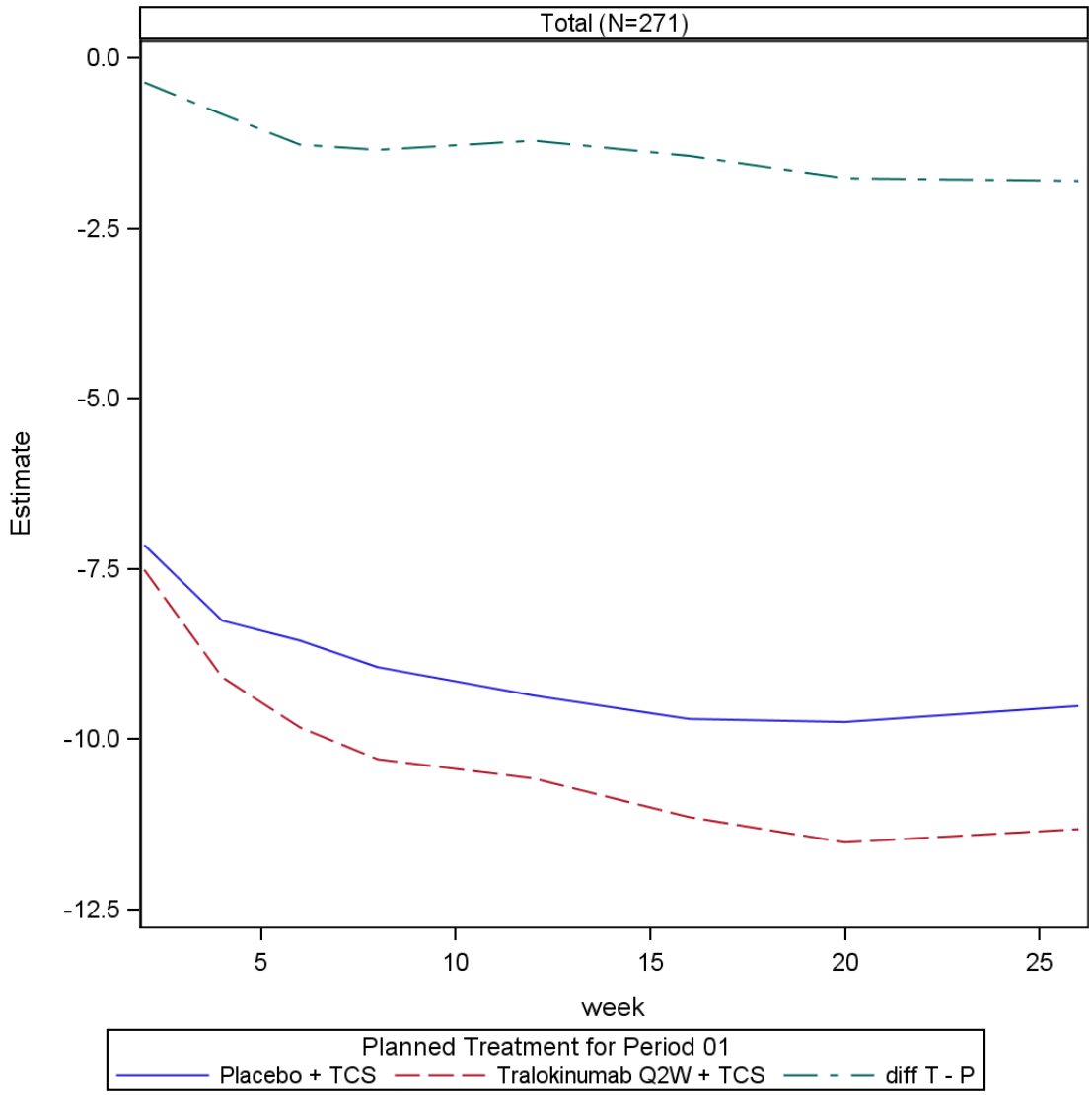
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.374.4.1: Total, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	6.2 (5.67)		111	4.1 (3.92)			
Week 20 chg	102	-9.9 (7.06)	-9.75 (0.42)	111	-11.4 (5.58)	-11.51 (0.41)	-1.77 (-2.93, -0.60) [-0.28 (-0.55, -0.01)]	0.003
Week 26	110	6.3 (5.26)		116	4.3 (4.31)			
Week 26 chg	110	-10.4 (6.56)	-9.51 (0.43)	116	-11.1 (6.17)	-11.32 (0.42)	-1.81 (-2.99, -0.62) [-0.28 (-0.55, -0.02)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.374.4.2: Total, change in DLQI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.375.4.1: Total, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total									
Total									
Baseline	137	134	20.9 (5.72)		138	135	21.3 (5.12)		
Week 2		130	15.1 (6.91)			130	13.5 (6.31)		
Week 2 chg		130	-5.9 (6.29)	-5.98 (0.49)		130	-7.7 (5.43)	-7.66 (0.49)	-1.67 (-3.03, -0.31) 0.016 [-0.28 (-0.53, -0.04)]
Week 4		130	13.8 (7.45)			133	11.6 (6.30)		
Week 4 chg		130	-7.1 (7.56)	-7.08 (0.55)		133	-9.7 (6.02)	-9.49 (0.55)	-2.41 (-3.94, -0.88) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123	13.5 (7.81)			124	10.9 (5.95)		
Week 6 chg		123	-7.2 (8.29)	-7.29 (0.58)		124	-10.6 (6.27)	-10.34 (0.58)	-3.04 (-4.67, -1.42) <.001 [-0.41 (-0.67, -0.16)]
Week 8		127	13.1 (7.02)			126	9.9 (5.79)		
Week 8 chg		127	-7.6 (7.95)	-7.72 (0.55)		126	-11.5 (6.10)	-11.11 (0.55)	-3.39 (-4.91, -1.86) <.001 [-0.48 (-0.73, -0.23)]
Week 12		123	13.0 (7.39)			122	9.2 (5.72)		
Week 12 chg		123	-8.0 (8.26)	-7.95 (0.57)		122	-12.4 (6.20)	-11.79 (0.57)	-3.84 (-5.43, -2.26) <.001 [-0.53 (-0.78, -0.27)]
Week 16		120	13.0 (7.69)			116	9.1 (5.58)		
Week 16 chg		120	-8.0 (8.09)	-8.10 (0.58)		116	-12.2 (6.39)	-11.82 (0.58)	-3.72 (-5.33, -2.11) <.001 [-0.51 (-0.77, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

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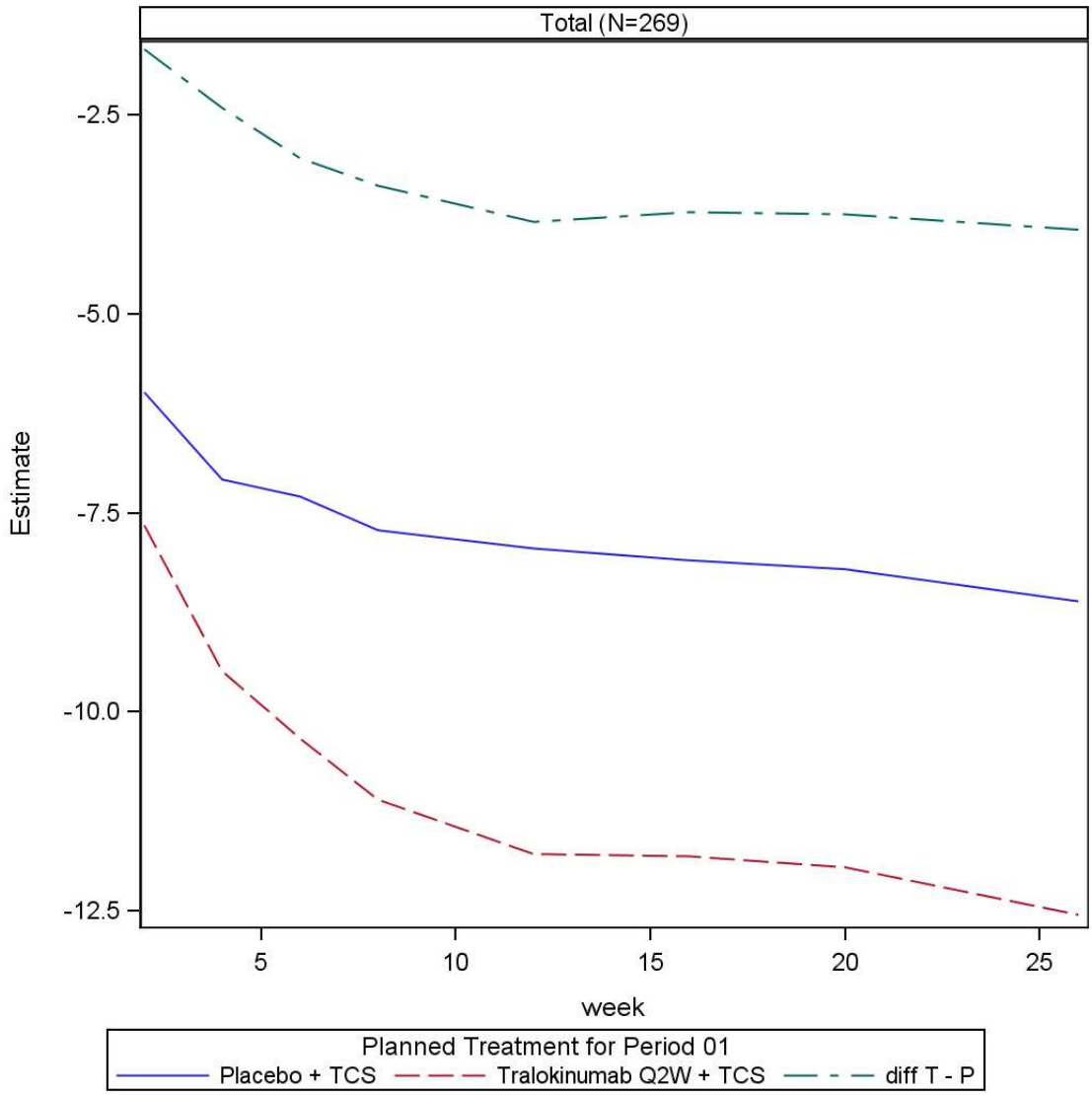
Table 1.1.375.4.1: Total, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	12.3 (7.64)		109	9.0 (5.60)			
Week 20 chg	102	-8.3 (7.60)	-8.21 (0.58)	109	-12.2 (6.08)	-11.96 (0.57)	-3.75 (-5.34, -2.15) [-0.55 (-0.82, -0.27)]	<.001
Week 26	110	11.8 (7.82)		114	8.2 (5.65)			
Week 26 chg	110	-8.9 (8.23)	-8.61 (0.61)	114	-12.8 (6.59)	-12.55 (0.60)	-3.94 (-5.62, -2.26) [-0.53 (-0.80, -0.26)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.375.4.2: Total, change in POEM, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.385.4.1: Total, SCORAD 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	13 (9.4)	4.5 (-1.61;10.59)	1.9 (0.78; 4.54)	2.0 (0.77; 5.17)	0.1522	
Placebo + TCS	137	7 (5.1)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

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Table 1.1.386.4.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.41 (0.22)		138 -2.8 (2.87)	-2.87 (0.22)	-0.46 (-1.07, 0.16) 0.145 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.22 (0.23)		137 -3.8 (2.99)	-3.80 (0.23)	-0.58 (-1.22, 0.06) 0.075 [-0.18 (-0.42, 0.05)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.15 (0.23)		134 -4.1 (2.81)	-4.07 (0.23)	-0.92 (-1.57, -0.28) 0.005 [-0.30 (-0.54, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.50 (0.22)		130 -4.4 (2.91)	-4.32 (0.22)	-0.82 (-1.44, -0.20) 0.009 [-0.26 (-0.51, -0.02)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.64 (0.23)		130 -4.5 (2.93)	-4.43 (0.23)	-0.80 (-1.44, -0.16) 0.015 [-0.25 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.73 (0.22)		128 -4.6 (2.96)	-4.55 (0.22)	-0.82 (-1.45, -0.20) 0.010 [-0.26 (-0.50, -0.01)]

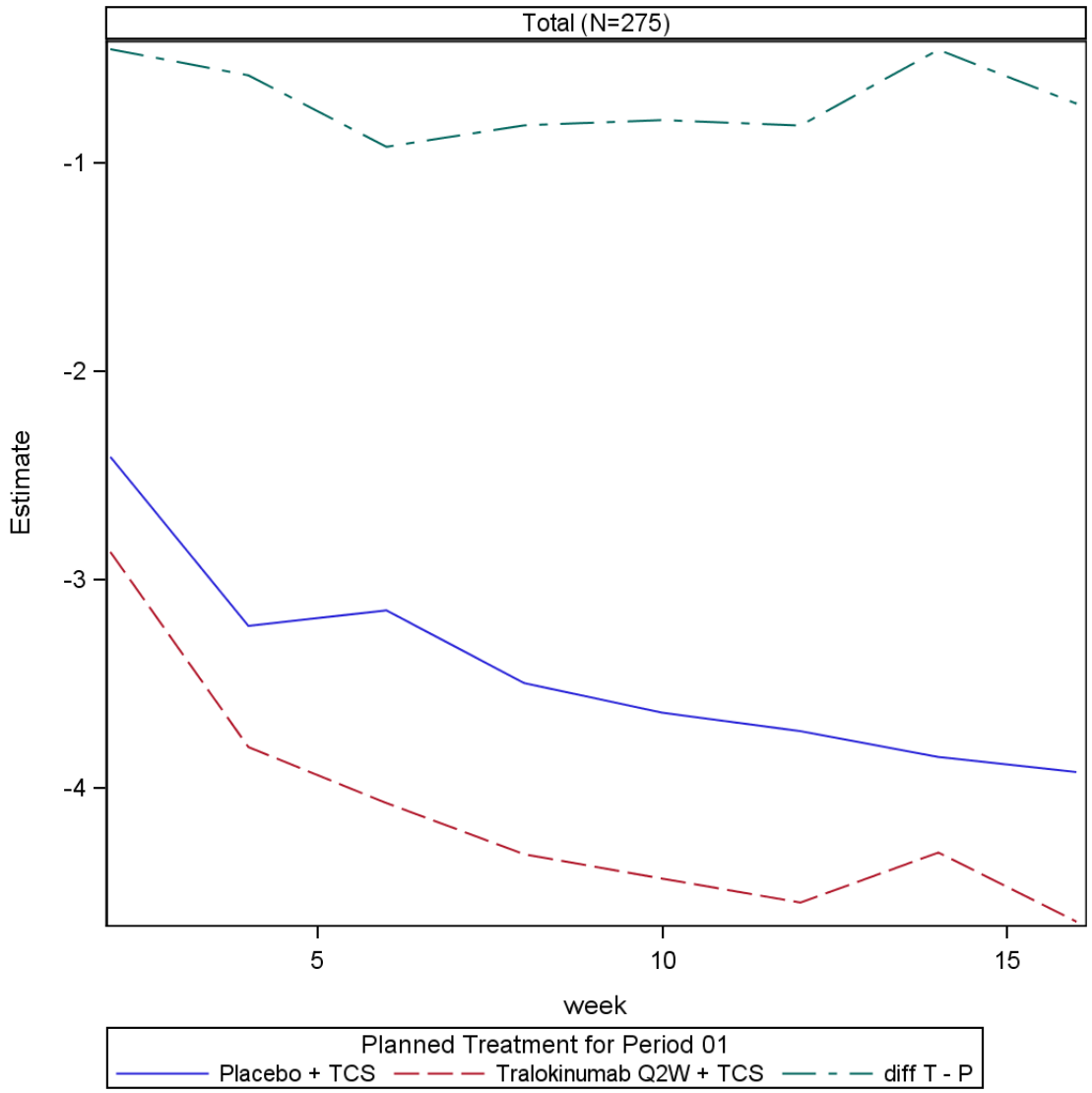
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.386.4.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	126	2.8 (2.94)		127	2.3 (2.60)			
Week 14 chg	126	-4.0 (3.48)	-3.85 (0.24)	127	-4.4 (3.07)	-4.31 (0.24)	-0.46 (-1.13, 0.21) [-0.14 (-0.39, 0.11)]	0.178
Week 16	124	2.7 (2.77)		123	1.9 (2.39)			
Week 16 chg	124	-4.1 (3.25)	-3.92 (0.22)	123	-4.7 (2.92)	-4.64 (0.22)	-0.72 (-1.34, -0.10) [-0.23 (-0.48, 0.02)]	0.024

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.386.4.2: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16



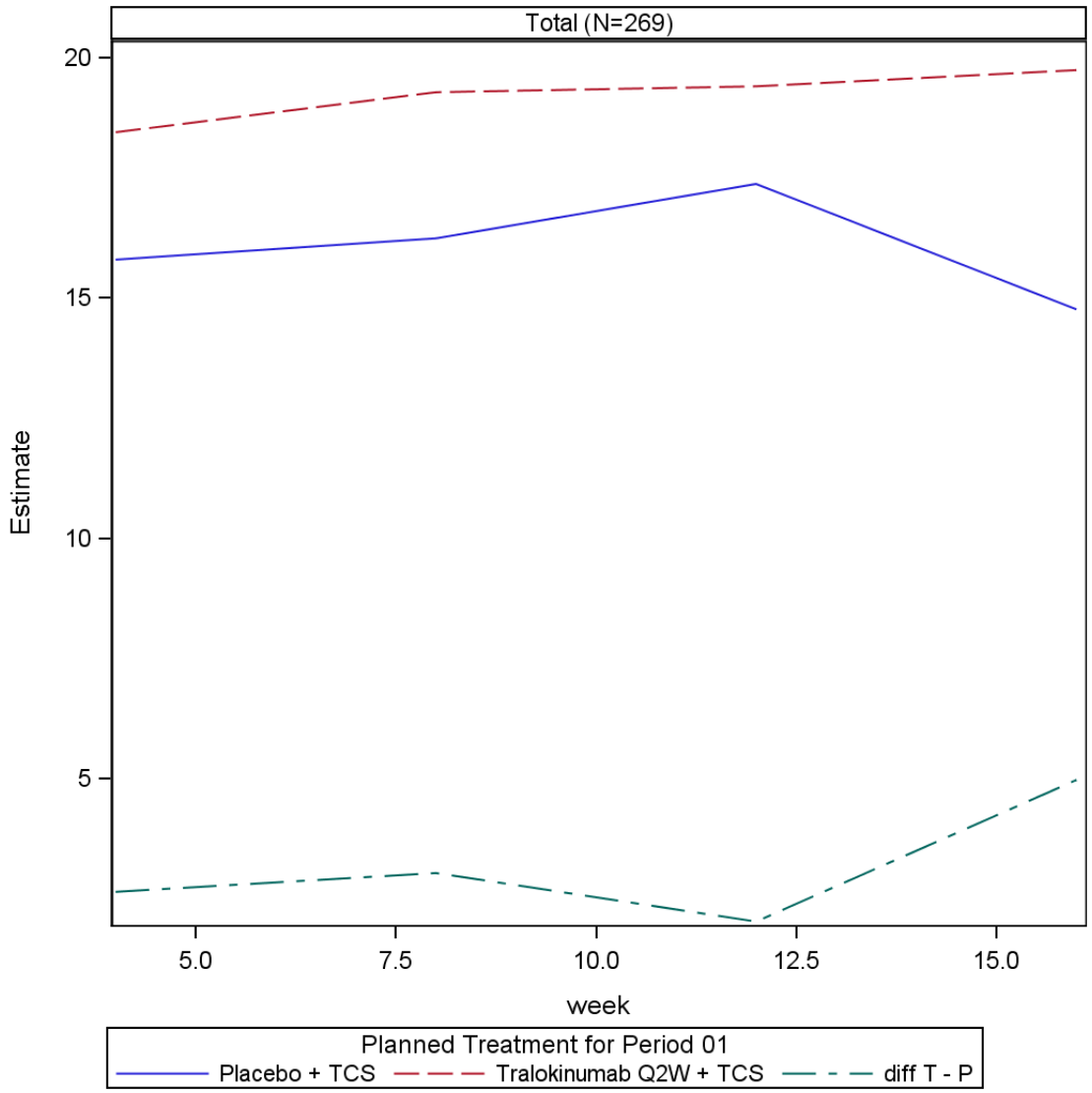
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Region + Baseline IGA. In case of no post-baseline assessments 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.388.4.1: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.80 (1.36)		133	17.3 (19.49)	18.45 (1.35)	2.65 (-1.14, 6.44) 0.170 [0.13 (-0.11, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.24 (1.51)		126	18.4 (21.17)	19.28 (1.51)	3.04 (-1.19, 7.27) 0.158 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.37 (1.49)		122	18.7 (21.48)	19.40 (1.49)	2.03 (-2.13, 6.19) 0.338 [0.09 (-0.16, 0.34)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.76 (1.74)		116	17.7 (22.49)	19.74 (1.76)	4.98 (0.08, 9.87) 0.046 [0.20 (-0.05, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.388.4.2: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.389.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)										
Total										
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)			
Week 16		123	4.2 (2.30)			124	3.3 (2.05)			
Week 16 chg		122	-3.3 (2.36)	-3.21 (0.19)		123	-3.9 (2.06)	-3.98 (0.19)	-0.77 (-1.30, -0.24) [-0.35 (-0.60, -0.10)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.390.4.1: Total, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 16		123 3.2 (2.41)			124 2.4 (2.16)		
Week 16 chg		122 -3.7 (2.29)	-3.50 (0.19)		123 -3.9 (2.32)	-4.03 (0.19)	-0.53 (-1.07, 0.01) 0.052 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.391.4.1: Total, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score									
Total									
Baseline	137	137	70.8 (12.84)		138	138	70.2 (12.05)		
Week 16		124	36.3 (18.78)			123	27.0 (16.90)		
Week 16 chg		124	-34.7 (19.94)	-34.36 (1.54)		123	-43.3 (19.46)	-43.61 (1.55)	-9.25 (-13.6, -4.94) <.001 [-0.47 (-0.72, -0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.392.4.1: Total, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 16		122 6.4 (5.60)			119 4.5 (3.87)		
Week 16 chg		120 -10.0 (6.54)	-9.61 (0.40)		118 -11.0 (5.99)	-11.29 (0.41)	-1.68 (-2.82, -0.55) 0.004 [-0.27 (-0.52, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.393.4.1: Total, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total										
Total										
Baseline	137	134	20.9 (5.72)		138	135	21.3 (5.12)			
Week 16		122	12.9 (7.67)			119	9.0 (5.53)			
Week 16 chg		120	-8.0 (8.09)	-8.10 (0.59)		116	-12.2 (6.39)	-12.12 (0.60)	-4.02 (-5.68, -2.36) [-0.55 (-0.81, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.395.4.1: Total, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 16		122	69.3 (21.69)			119	75.7 (16.92)		
Week 16 chg		120	16.7 (26.74)	14.64 (1.75)		116	17.7 (22.49)	19.84 (1.78)	5.21 (0.28, 10.14) 0.039 [0.21 (-0.05, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.396.4.1: Total, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 16		124 2.7 (2.77)			123 1.9 (2.39)		
Week 16 chg		124 -4.1 (3.25)	-3.99 (0.23)		123 -4.7 (2.92)	-4.72 (0.23)	-0.73 (-1.36, -0.09) 0.025 [-0.23 (-0.48, 0.02)]

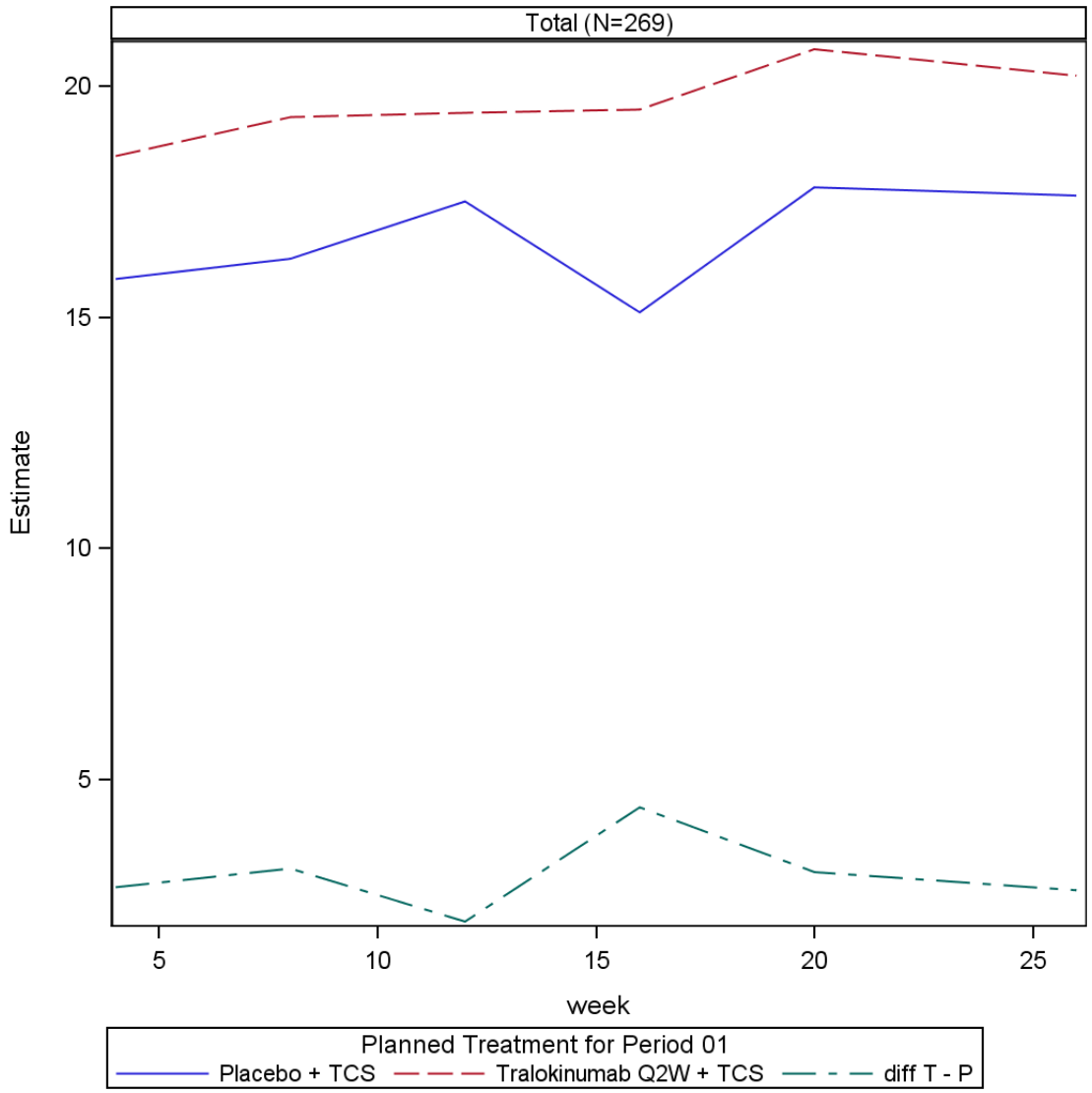
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.397.4.1: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.83 (1.36)		133	17.3 (19.49)	18.49 (1.35)	2.66 (-1.12, 6.45) 0.168 [0.13 (-0.11, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.27 (1.51)		126	18.4 (21.17)	19.33 (1.51)	3.07 (-1.16, 7.29) 0.154 [0.13 (-0.11, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.51 (1.49)		122	18.7 (21.48)	19.43 (1.49)	1.92 (-2.24, 6.08) 0.365 [0.09 (-0.16, 0.34)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	15.11 (1.72)		116	17.7 (22.49)	19.50 (1.74)	4.39 (-0.44, 9.22) 0.074 [0.18 (-0.08, 0.43)]
Week 20		103	72.7 (20.07)			108	77.3 (14.52)		
Week 20 chg		103	19.3 (25.56)	17.81 (1.58)		108	21.6 (20.57)	20.80 (1.57)	2.99 (-1.40, 7.38) 0.181 [0.13 (-0.14, 0.40)]
Week 26		113	72.4 (20.84)			116	76.4 (17.02)		
Week 26 chg		113	20.5 (25.83)	17.63 (1.69)		116	19.5 (21.18)	20.23 (1.67)	2.59 (-2.10, 7.29) 0.277 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.397.4.2: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.398.4.1: Total, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 26		115	72.6 (20.73)			119	76.4 (17.30)		
Week 26 chg		113	20.5 (25.83)	18.74 (1.72)		116	19.5 (21.18)	21.31 (1.70)	2.56 (-2.22, 7.35) 0.292 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.401.4.1: Total, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.56 (0.82)		138 -12.9 (10.72)	-13.28 (0.82)	-0.72 (-3.02, 1.57) 0.536 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.48 (0.83)		137 -18.8 (10.58)	-19.37 (0.82)	-1.88 (-4.18, 0.42) 0.109 [-0.17 (-0.41, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.42 (0.83)		134 -20.9 (11.93)	-21.43 (0.83)	-3.01 (-5.32, -0.70) 0.011 [-0.25 (-0.49, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.19 (0.83)		130 -22.5 (12.16)	-23.11 (0.83)	-3.92 (-6.23, -1.60) <.001 [-0.30 (-0.54, -0.06)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.50 (0.83)		130 -24.3 (11.55)	-24.96 (0.83)	-4.46 (-6.78, -2.14) <.001 [-0.35 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-20.99 (0.84)		128 -24.7 (12.40)	-25.11 (0.84)	-4.13 (-6.46, -1.80) <.001 [-0.31 (-0.56, -0.06)]

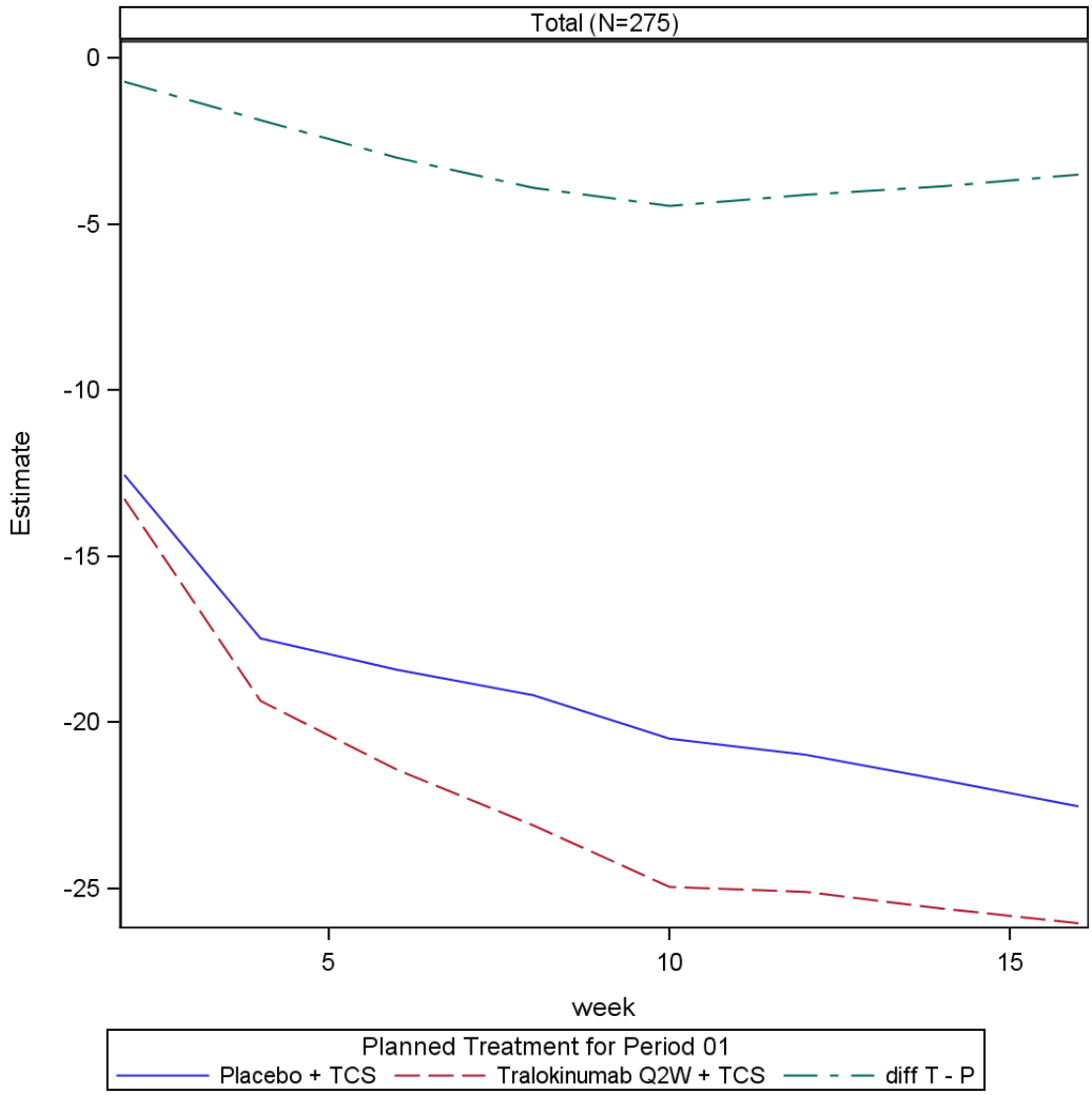
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.401.4.1: Total, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	11.2 (11.57)		127	7.0 (8.34)		
Week 14 chg	126	-22.8 (14.69)	-21.74 (0.84)	127	-25.1 (13.29)	-25.62 (0.84)	-3.87 (-6.21, -1.54) 0.001 [-0.28 (-0.52, -0.03)]
Week 16	124	10.5 (11.42)		123	6.4 (7.63)		
Week 16 chg	124	-23.8 (14.93)	-22.54 (0.84)	123	-25.9 (12.78)	-26.06 (0.84)	-3.52 (-5.86, -1.17) 0.003 [-0.25 (-0.50, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.401.4.2: Total, change in EASI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.1.403.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)										
Total										
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)			
Week 1		135	6.3 (1.69)			136	6.0 (1.78)			
Week 1 chg		135	-1.1 (1.34)	-1.14 (0.17)		136	-1.2 (1.31)	-1.23 (0.17)	-0.08 (-0.56, 0.39) [-0.06 (-0.30, 0.18)]	0.732
Week 2		134	5.8 (1.97)			132	5.4 (2.11)			
Week 2 chg		134	-1.7 (1.78)	-1.67 (0.17)		132	-1.9 (1.67)	-1.92 (0.17)	-0.24 (-0.72, 0.24) [-0.14 (-0.38, 0.10)]	0.324
Week 3		133	5.3 (2.17)			131	4.8 (2.08)			
Week 3 chg		133	-2.2 (2.12)	-2.11 (0.17)		131	-2.5 (1.84)	-2.53 (0.17)	-0.42 (-0.90, 0.06) [-0.21 (-0.45, 0.03)]	0.088
Week 4		130	5.1 (2.25)			133	4.4 (2.14)			
Week 4 chg		130	-2.4 (2.14)	-2.29 (0.17)		133	-2.8 (1.92)	-2.87 (0.17)	-0.58 (-1.06, -0.10) [-0.28 (-0.53, -0.04)]	0.019
Week 5		131	4.9 (2.37)			129	4.2 (2.15)			
Week 5 chg		131	-2.6 (2.26)	-2.54 (0.17)		129	-3.1 (1.92)	-3.16 (0.17)	-0.62 (-1.10, -0.14) [-0.30 (-0.54, -0.05)]	0.012
Week 6		130	4.8 (2.35)			129	4.2 (2.16)			
Week 6 chg		130	-2.7 (2.25)	-2.58 (0.17)		129	-3.1 (1.99)	-3.14 (0.17)	-0.57 (-1.05, -0.08) [-0.27 (-0.51, -0.02)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.403.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	4.7 (2.24)		128	4.0 (2.13)			
Week 7 chg	129	-2.8 (2.25)	-2.73 (0.17)	128	-3.3 (2.05)	-3.38 (0.17)	-0.65 (-1.13, -0.16) [-0.30 (-0.55, -0.05)]	0.009
Week 8	127	4.7 (2.32)		125	3.7 (2.10)			
Week 8 chg	127	-2.8 (2.27)	-2.73 (0.17)	125	-3.7 (1.96)	-3.64 (0.17)	-0.92 (-1.40, -0.43) [-0.43 (-0.68, -0.18)]	<.001
Week 9	127	4.6 (2.37)		127	3.6 (2.10)			
Week 9 chg	127	-2.9 (2.32)	-2.79 (0.17)	127	-3.7 (2.03)	-3.71 (0.17)	-0.92 (-1.40, -0.44) [-0.42 (-0.67, -0.17)]	<.001
Week 10	125	4.5 (2.42)		122	3.6 (2.11)			
Week 10 chg	125	-2.9 (2.39)	-2.87 (0.17)	122	-3.7 (1.93)	-3.70 (0.17)	-0.83 (-1.32, -0.35) [-0.38 (-0.63, -0.13)]	<.001
Week 11	128	4.4 (2.41)		126	3.5 (2.15)			
Week 11 chg	128	-3.1 (2.40)	-3.06 (0.17)	126	-3.7 (1.97)	-3.75 (0.17)	-0.70 (-1.18, -0.21) [-0.32 (-0.56, -0.07)]	0.005
Week 12	123	4.4 (2.36)		121	3.5 (2.08)			
Week 12 chg	123	-3.1 (2.41)	-3.03 (0.17)	121	-3.8 (2.06)	-3.82 (0.17)	-0.80 (-1.28, -0.31) [-0.35 (-0.61, -0.10)]	0.001
Week 13	116	4.3 (2.38)		120	3.3 (2.06)			
Week 13 chg	116	-3.3 (2.35)	-3.09 (0.18)	120	-4.0 (2.09)	-3.92 (0.17)	-0.84 (-1.32, -0.35) [-0.38 (-0.63, -0.12)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

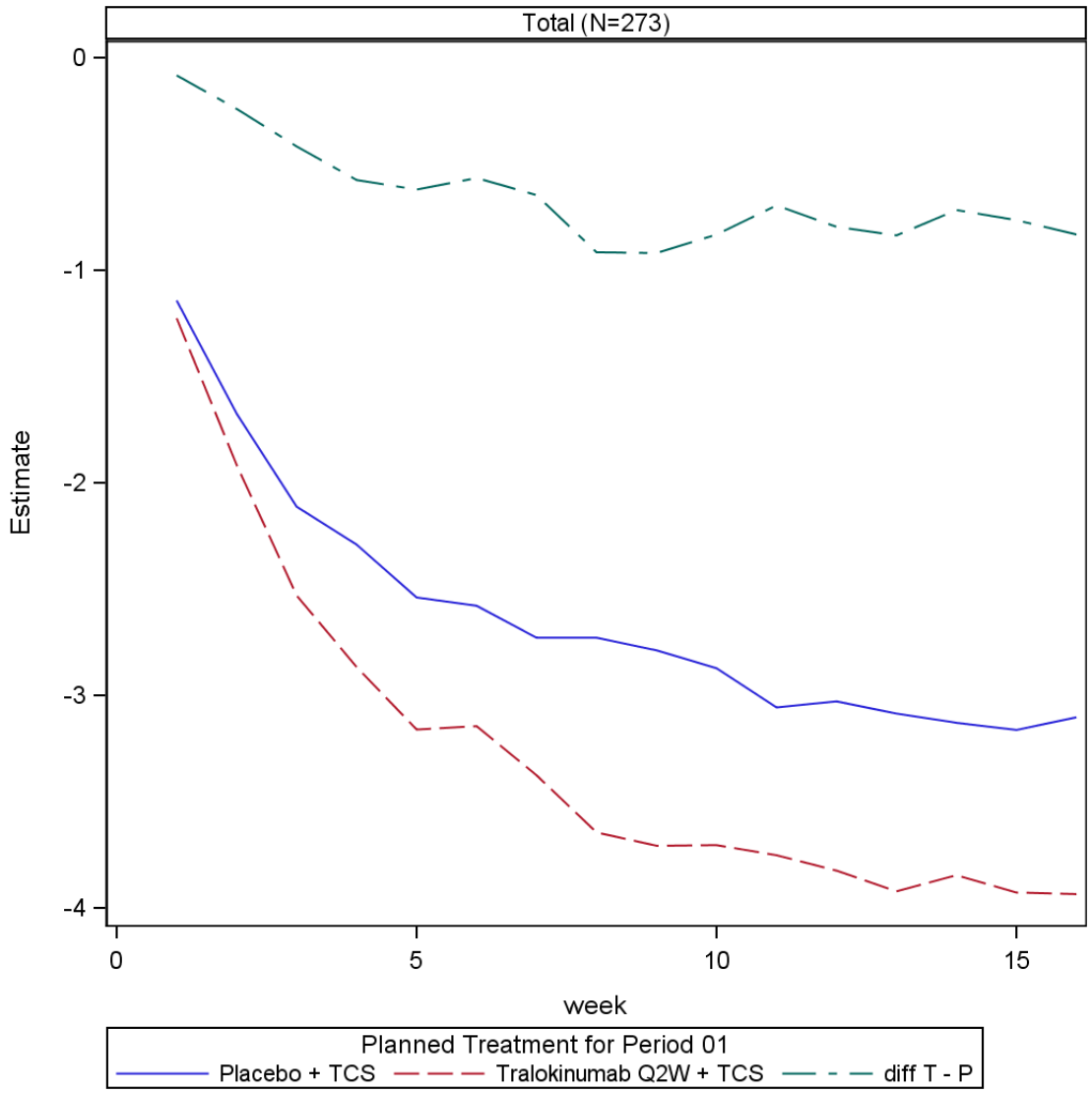
12MAY21 12:08 LP0162-Payer /p_mmrm3/t_t_total_g03_46_w16.txt

Table 1.1.403.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	123	4.2 (2.38)		123	3.4 (2.13)		
Week 14 chg	123	-3.3 (2.33)	-3.13 (0.17)	123	-3.9 (2.12)	-3.85 (0.17)	-0.72 (-1.20, -0.23) 0.004 [-0.32 (-0.57, -0.07)]
Week 15	123	4.2 (2.31)		123	3.4 (2.11)		
Week 15 chg	123	-3.3 (2.32)	-3.16 (0.17)	123	-4.0 (2.15)	-3.93 (0.17)	-0.76 (-1.25, -0.28) 0.002 [-0.34 (-0.59, -0.09)]
Week 16	121	4.2 (2.29)		122	3.4 (2.05)		
Week 16 chg	121	-3.3 (2.35)	-3.10 (0.17)	122	-3.9 (2.06)	-3.93 (0.17)	-0.83 (-1.32, -0.35) <.001 [-0.38 (-0.63, -0.12)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.403.4.2: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.1.405.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 1		135 5.8 (2.01)			136 5.2 (2.21)		
Week 1 chg		135 -1.1 (1.50)	-1.07 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.08 (-0.58, 0.42) 0.756 [-0.05 (-0.29, 0.18)]
Week 2		134 5.2 (2.29)			132 4.5 (2.45)		
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.18)	-0.18 (-0.68, 0.33) 0.493 [-0.09 (-0.33, 0.15)]
Week 3		133 4.7 (2.36)			131 3.9 (2.35)		
Week 3 chg		133 -2.2 (2.17)	-2.13 (0.18)		131 -2.4 (2.01)	-2.49 (0.18)	-0.36 (-0.86, 0.14) 0.160 [-0.17 (-0.41, 0.07)]
Week 4		130 4.5 (2.48)			133 3.6 (2.39)		
Week 4 chg		130 -2.4 (2.23)	-2.26 (0.18)		133 -2.7 (2.06)	-2.79 (0.18)	-0.53 (-1.03, -0.03) 0.038 [-0.25 (-0.49, -0.01)]
Week 5		131 4.2 (2.55)			129 3.3 (2.42)		
Week 5 chg		131 -2.7 (2.37)	-2.56 (0.18)		129 -3.0 (2.16)	-3.14 (0.18)	-0.58 (-1.08, -0.07) 0.024 [-0.25 (-0.50, -0.01)]
Week 6		130 4.2 (2.52)			129 3.3 (2.42)		
Week 6 chg		130 -2.7 (2.36)	-2.53 (0.18)		129 -3.1 (2.24)	-3.20 (0.18)	-0.67 (-1.17, -0.17) 0.009 [-0.29 (-0.54, -0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.405.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	129 3.9 (2.43)		128	128 3.1 (2.37)		
Week 7 chg	129	129 -3.0 (2.38)	-2.81 (0.18)	128	128 -3.3 (2.28)	-3.41 (0.18)	-0.60 (-1.10, -0.10) 0.020 [-0.26 (-0.50, -0.01)]
Week 8	127	127 3.9 (2.46)		125	125 2.8 (2.29)		
Week 8 chg	127	127 -3.0 (2.32)	-2.79 (0.18)	125	125 -3.6 (2.26)	-3.65 (0.18)	-0.86 (-1.36, -0.35) <.001 [-0.37 (-0.62, -0.12)]
Week 9	127	127 3.8 (2.49)		127	127 2.6 (2.22)		
Week 9 chg	127	127 -3.1 (2.33)	-2.92 (0.18)	127	127 -3.7 (2.23)	-3.83 (0.18)	-0.91 (-1.41, -0.40) <.001 [-0.40 (-0.65, -0.15)]
Week 10	125	125 3.7 (2.54)		122	122 2.7 (2.29)		
Week 10 chg	125	125 -3.2 (2.40)	-3.04 (0.18)	122	122 -3.7 (2.29)	-3.82 (0.18)	-0.79 (-1.29, -0.28) 0.002 [-0.33 (-0.59, -0.08)]
Week 11	128	128 3.6 (2.46)		126	126 2.6 (2.22)		
Week 11 chg	128	128 -3.3 (2.40)	-3.15 (0.18)	126	126 -3.8 (2.26)	-3.89 (0.18)	-0.75 (-1.25, -0.24) 0.004 [-0.32 (-0.57, -0.07)]
Week 12	123	123 3.5 (2.44)		121	121 2.5 (2.21)		
Week 12 chg	123	123 -3.4 (2.45)	-3.18 (0.18)	121	121 -3.8 (2.38)	-4.01 (0.18)	-0.82 (-1.33, -0.31) 0.002 [-0.34 (-0.59, -0.09)]
Week 13	116	116 3.4 (2.40)		120	120 2.3 (2.13)		
Week 13 chg	116	116 -3.6 (2.32)	-3.32 (0.18)	120	120 -3.9 (2.26)	-4.05 (0.18)	-0.74 (-1.25, -0.23) 0.005 [-0.32 (-0.58, -0.06)]

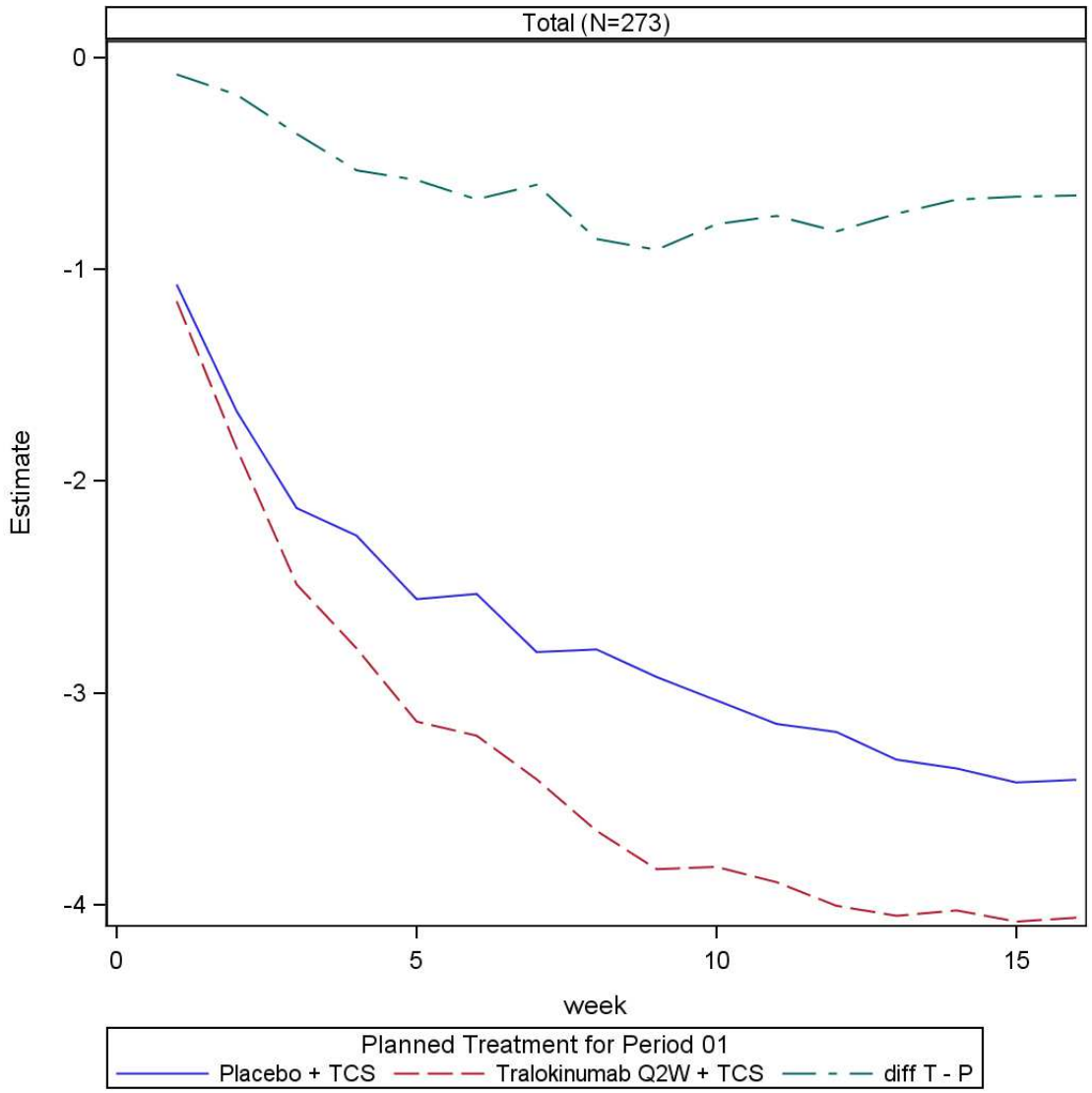
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.405.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	3.3 (2.42)		123	2.4 (2.18)			
Week 14 chg	123	-3.5 (2.33)	-3.36 (0.18)	123	-3.9 (2.27)	-4.03 (0.18)	-0.67 (-1.18, -0.16) [-0.29 (-0.54, -0.04)]	0.010
Week 15	123	3.3 (2.47)		123	2.4 (2.18)			
Week 15 chg	123	-3.7 (2.35)	-3.42 (0.18)	123	-3.9 (2.35)	-4.08 (0.18)	-0.66 (-1.16, -0.15) [-0.28 (-0.53, -0.03)]	0.011
Week 16	121	3.2 (2.40)		122	2.5 (2.17)			
Week 16 chg	121	-3.7 (2.28)	-3.41 (0.18)	122	-3.9 (2.32)	-4.06 (0.18)	-0.65 (-1.16, -0.14) [-0.28 (-0.54, -0.03)]	0.012

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.405.4.2: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.1.407.4.1: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.22 (1.49)		138 -20.9 (16.72)	-21.06 (1.48)	-3.84 (-7.97, 0.30) 0.069 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.25 (1.50)		137 -30.8 (17.25)	-31.00 (1.49)	-4.75 (-8.90, -0.60) 0.025 [-0.27 (-0.51, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.77 (1.50)		134 -34.3 (17.49)	-34.45 (1.49)	-7.67 (-11.8, -3.51) <.001 [-0.42 (-0.66, -0.18)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.63 (1.50)		130 -36.6 (18.48)	-36.80 (1.50)	-8.16 (-12.3, -3.99) <.001 [-0.43 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.78 (1.50)		130 -38.5 (19.49)	-38.59 (1.50)	-7.81 (-12.0, -3.63) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.51 (1.51)		128 -39.5 (18.74)	-39.57 (1.51)	-8.06 (-12.3, -3.87) <.001 [-0.42 (-0.67, -0.17)]

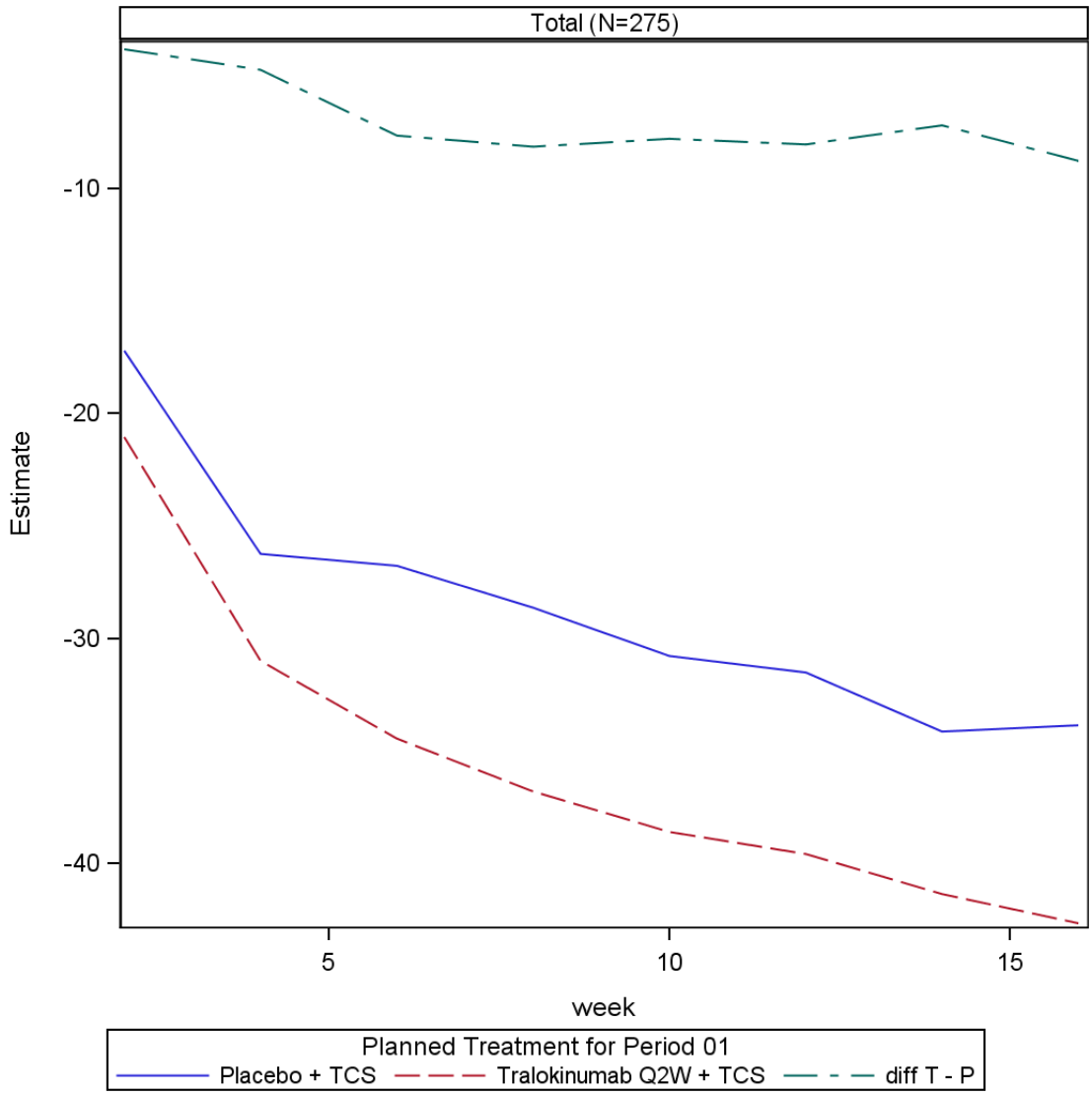
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.407.4.1: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14		126 36.0 (19.61)			127 28.3 (17.87)			
Week 14 chg		126 -34.8 (20.31)	-34.13 (1.52)		127 -41.8 (20.11)	-41.35 (1.51)	-7.22 (-11.4, -3.01) [-0.36 (-0.61, -0.11)]	<.001
Week 16		124 36.3 (18.78)			123 27.0 (16.90)			
Week 16 chg		124 -34.7 (19.94)	-33.86 (1.52)		123 -43.3 (19.46)	-42.65 (1.52)	-8.79 (-13.0, -4.57) [-0.45 (-0.70, -0.19)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.407.4.2: Total, change in SCORAD, Treatment policy, LP0162-1346, 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 Prior CSA use, 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.

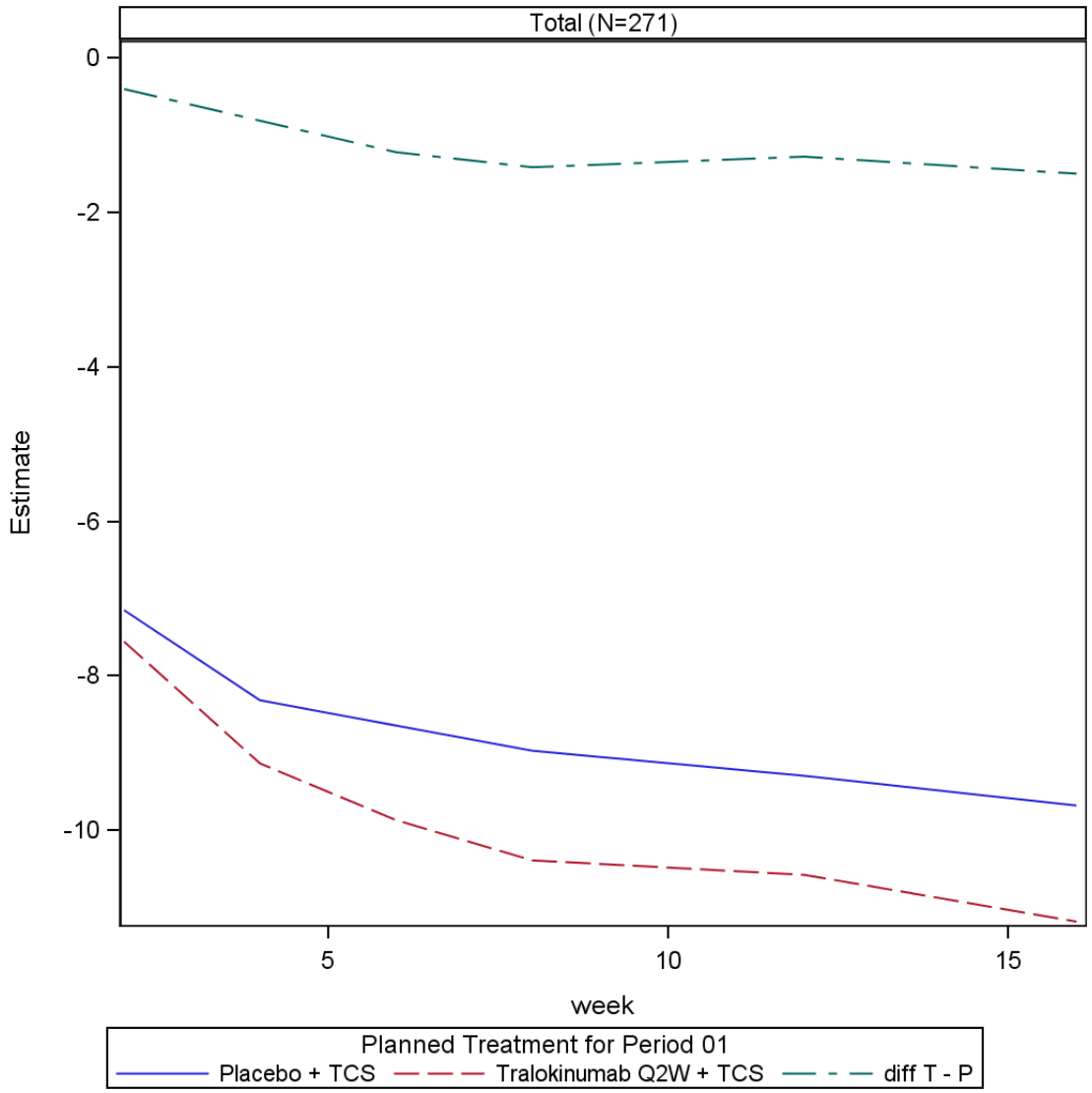
Table 1.1.409.4.1: Total, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score										
Total										
Baseline	137	134	16.4 (6.33)		138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)			132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.15 (0.45)		132	-7.5 (5.92)	-7.56 (0.45)	-0.41 (-1.65, 0.84) [-0.07 (-0.31, 0.17)]	0.520
Week 4		130	7.8 (6.27)			135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.32 (0.45)		135	-9.0 (6.32)	-9.14 (0.44)	-0.82 (-2.06, 0.42) [-0.13 (-0.37, 0.12)]	0.196
Week 6		123	7.3 (6.07)			126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.65 (0.45)		126	-10.0 (6.75)	-9.87 (0.45)	-1.22 (-2.48, 0.03) [-0.18 (-0.42, 0.07)]	0.056
Week 8		127	6.9 (5.70)			128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.97 (0.45)		128	-10.6 (6.29)	-10.39 (0.45)	-1.42 (-2.67, -0.17) [-0.22 (-0.46, 0.03)]	0.026
Week 12		123	6.8 (5.89)			124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.30 (0.46)		124	-10.6 (5.77)	-10.58 (0.45)	-1.28 (-2.54, -0.02) [-0.20 (-0.45, 0.05)]	0.046
Week 16		120	6.5 (5.63)			118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.46)		118	-11.0 (5.99)	-11.18 (0.46)	-1.50 (-2.77, -0.23) [-0.24 (-0.49, 0.02)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 16:43 LP0162-Payer /p_mmrm3/t_t_total_g09_46_w16.txt

Figure 1.1.409.4.2: Total, change in DLQI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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.

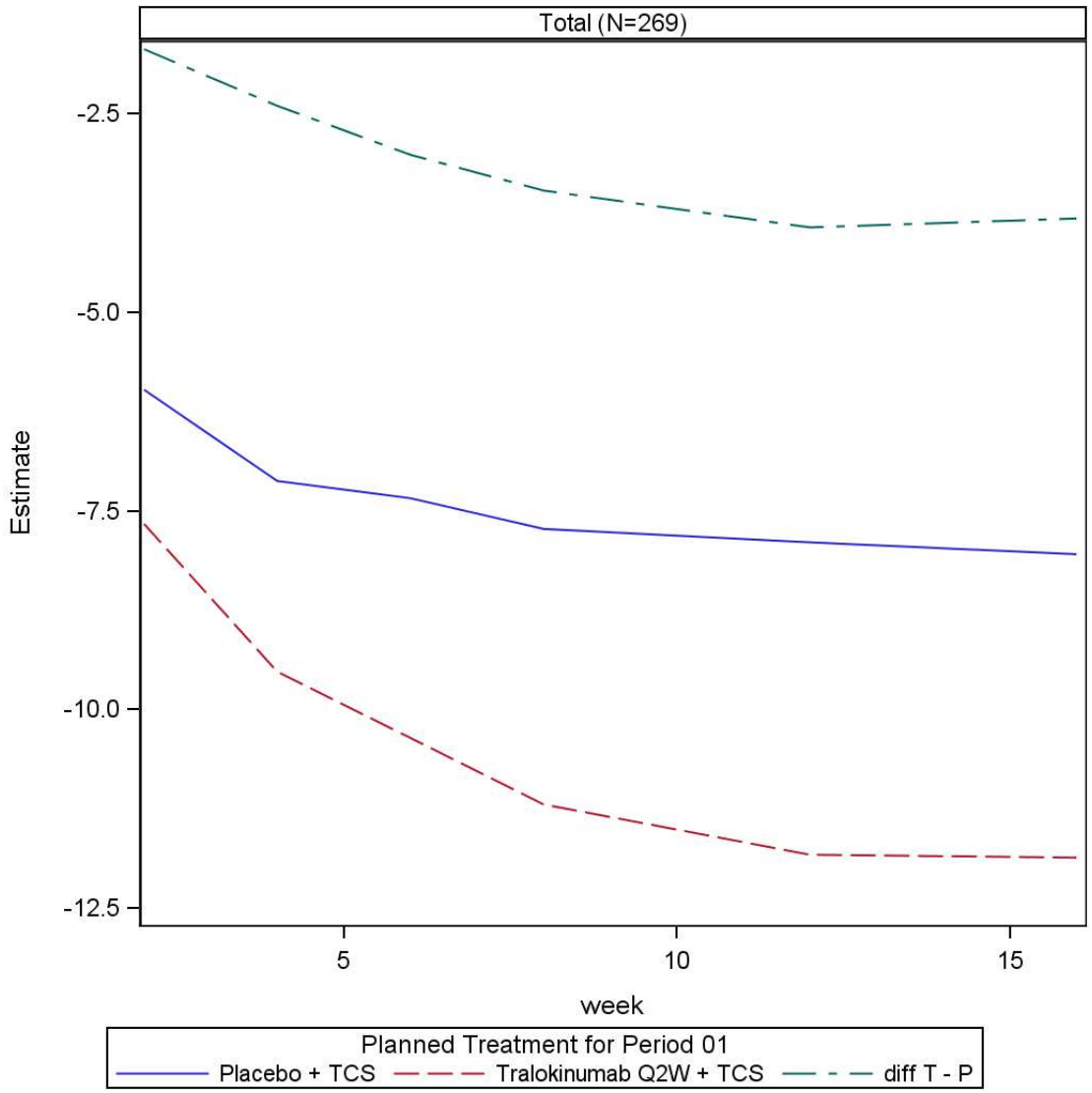
Table 1.1.410.4.1: Total, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 2		130 15.1 (6.91)			130 13.5 (6.31)			
Week 2 chg		130 -5.9 (6.29)	-5.98 (0.55)		130 -7.7 (5.43)	-7.66 (0.54)	-1.69 (-3.20, -0.17)	0.029
							[-0.29 (-0.53, -0.04)]	
Week 4		130 13.8 (7.45)			133 11.6 (6.30)			
Week 4 chg		130 -7.1 (7.56)	-7.12 (0.55)		133 -9.7 (6.02)	-9.53 (0.54)	-2.40 (-3.92, -0.89)	0.002
							[-0.35 (-0.60, -0.11)]	
Week 6		123 13.5 (7.81)			124 10.9 (5.95)			
Week 6 chg		123 -7.2 (8.29)	-7.34 (0.55)		124 -10.6 (6.27)	-10.36 (0.55)	-3.02 (-4.56, -1.48)	<.001
							[-0.41 (-0.66, -0.16)]	
Week 8		127 13.1 (7.02)			126 9.9 (5.79)			
Week 8 chg		127 -7.6 (7.95)	-7.73 (0.55)		126 -11.5 (6.10)	-11.20 (0.55)	-3.47 (-5.00, -1.94)	<.001
							[-0.49 (-0.74, -0.24)]	
Week 12		123 13.0 (7.39)			122 9.2 (5.72)			
Week 12 chg		123 -8.0 (8.26)	-7.90 (0.55)		122 -12.4 (6.20)	-11.83 (0.55)	-3.93 (-5.47, -2.39)	<.001
							[-0.54 (-0.79, -0.28)]	
Week 16		120 13.0 (7.69)			116 9.1 (5.58)			
Week 16 chg		120 -8.0 (8.09)	-8.05 (0.56)		116 -12.2 (6.39)	-11.87 (0.56)	-3.82 (-5.37, -2.27)	<.001
							[-0.52 (-0.78, -0.26)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 13:09 LP0162-Payer /p_mmrm3/t_t_total_g10_46_w16.txt

Figure 1.1.410.4.2: Total, change in POEM, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.1.414.4.1: Total, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.60 (0.81)		138 -12.9 (10.72)	-13.33 (0.81)	-0.73 (-2.98, 1.53) 0.526 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.57 (0.81)		137 -18.8 (10.58)	-19.44 (0.81)	-1.86 (-4.13, 0.40) 0.106 [-0.17 (-0.40, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.53 (0.82)		134 -20.9 (11.93)	-21.51 (0.81)	-2.98 (-5.25, -0.71) 0.010 [-0.24 (-0.48, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.30 (0.82)		130 -22.5 (12.16)	-23.17 (0.82)	-3.88 (-6.15, -1.60) <.001 [-0.30 (-0.54, -0.05)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.61 (0.82)		130 -24.3 (11.55)	-25.02 (0.82)	-4.41 (-6.69, -2.13) <.001 [-0.34 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-21.10 (0.82)		128 -24.7 (12.40)	-25.22 (0.82)	-4.11 (-6.40, -1.83) <.001 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 14:19 LP0162-Payer /p_mmrm3/t_t_total_g14_46_w26.txt

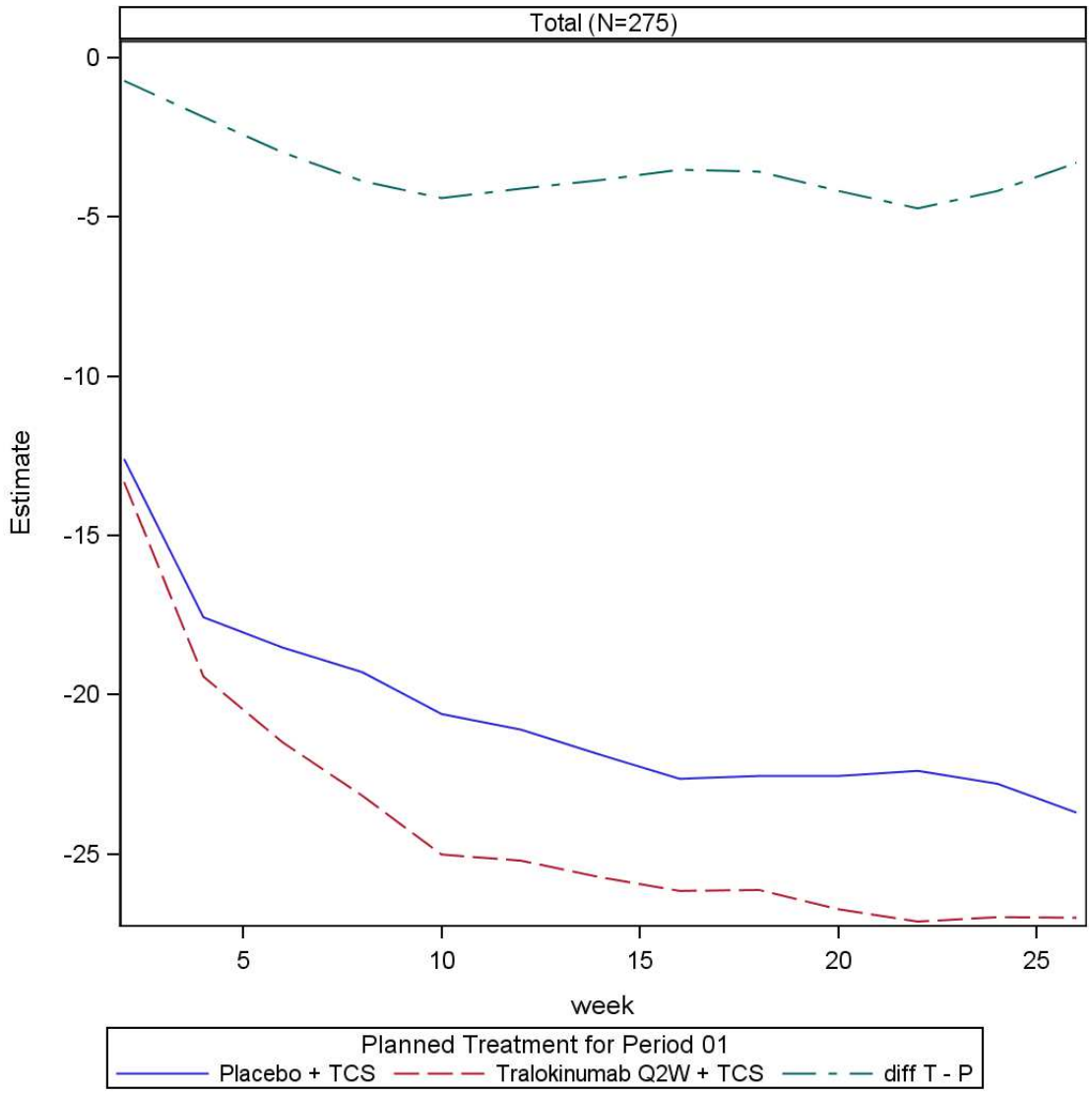
Table 1.1.414.4.1: Total, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	11.2 (11.57)		127	7.0 (8.34)		
Week 14 chg	126	-22.8 (14.69)	-21.89 (0.82)	127	-25.1 (13.29)	-25.74 (0.82)	-3.85 (-6.14, -1.55) 0.001 [-0.27 (-0.52, -0.03)]
Week 16	124	10.5 (11.42)		123	6.4 (7.63)		
Week 16 chg	124	-23.8 (14.93)	-22.65 (0.83)	123	-25.9 (12.78)	-26.17 (0.83)	-3.52 (-5.82, -1.22) 0.003 [-0.25 (-0.50, -0.00)]
Week 18	116	10.7 (11.52)		115	5.9 (7.36)		
Week 18 chg	116	-23.6 (14.71)	-22.56 (0.84)	115	-26.4 (12.11)	-26.14 (0.84)	-3.58 (-5.91, -1.25) 0.003 [-0.27 (-0.52, -0.01)]
Week 20	107	10.6 (12.56)		117	5.5 (6.56)		
Week 20 chg	107	-24.1 (15.32)	-22.56 (0.85)	117	-26.9 (11.94)	-26.74 (0.84)	-4.18 (-6.53, -1.84) <.001 [-0.31 (-0.57, -0.04)]
Week 22	112	10.5 (11.17)		114	5.0 (5.93)		
Week 22 chg	112	-24.3 (14.63)	-22.40 (0.84)	114	-27.3 (12.17)	-27.13 (0.84)	-4.73 (-7.08, -2.39) <.001 [-0.35 (-0.61, -0.09)]
Week 24	112	9.9 (11.00)		117	5.3 (7.21)		
Week 24 chg	112	-24.9 (14.38)	-22.80 (0.84)	117	-27.0 (12.11)	-26.99 (0.84)	-4.19 (-6.53, -1.85) <.001 [-0.32 (-0.58, -0.06)]
Week 26	118	9.1 (10.14)		125	5.6 (7.90)		
Week 26 chg	118	-25.5 (13.74)	-23.71 (0.83)	125	-26.5 (12.83)	-27.01 (0.82)	-3.30 (-5.61, -0.99) 0.005 [-0.25 (-0.50, 0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 14:19 LP0162-Payer /p_mmrm3/t_t_total_g14_46_w26.txt

Figure 1.1.414.4.2: Total, change in EASI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.1.416.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)			
Week 1		135 6.3 (1.69)			136 6.0 (1.78)			
Week 1 chg		135 -1.1 (1.34)	-1.12 (0.18)		136 -1.2 (1.31)	-1.22 (0.18)	-0.10 (-0.60, 0.40) [-0.07 (-0.31, 0.16)]	0.699
Week 2		134 5.8 (1.97)			132 5.4 (2.11)			
Week 2 chg		134 -1.7 (1.78)	-1.67 (0.18)		132 -1.9 (1.67)	-1.92 (0.18)	-0.24 (-0.74, 0.26) [-0.14 (-0.38, 0.10)]	0.338
Week 3		133 5.3 (2.17)			131 4.8 (2.08)			
Week 3 chg		133 -2.2 (2.12)	-2.11 (0.18)		131 -2.5 (1.84)	-2.53 (0.18)	-0.42 (-0.92, 0.08) [-0.21 (-0.46, 0.03)]	0.097
Week 4		130 5.1 (2.25)			133 4.4 (2.14)			
Week 4 chg		130 -2.4 (2.14)	-2.29 (0.18)		133 -2.8 (1.92)	-2.87 (0.18)	-0.58 (-1.08, -0.08) [-0.29 (-0.53, -0.04)]	0.023
Week 5		131 4.9 (2.37)			129 4.2 (2.15)			
Week 5 chg		131 -2.6 (2.26)	-2.53 (0.18)		129 -3.1 (1.92)	-3.16 (0.18)	-0.63 (-1.13, -0.13) [-0.30 (-0.54, -0.06)]	0.014
Week 6		130 4.8 (2.35)			129 4.2 (2.16)			
Week 6 chg		130 -2.7 (2.25)	-2.55 (0.18)		129 -3.1 (1.99)	-3.15 (0.18)	-0.61 (-1.11, -0.10) [-0.29 (-0.53, -0.04)]	0.018

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 14:26 LP0162-Payer /p_mmrm3/t_t_total_g16_46_w26.txt

Table 1.1.416.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	4.7 (2.24)		128	4.0 (2.13)		
Week 7 chg	129	-2.8 (2.25)	-2.69 (0.18)	128	-3.3 (2.05)	-3.38 (0.18)	-0.69 (-1.19, -0.19) 0.007 [-0.32 (-0.57, -0.07)]
Week 8	127	4.7 (2.32)		125	3.7 (2.10)		
Week 8 chg	127	-2.8 (2.27)	-2.69 (0.18)	125	-3.7 (1.96)	-3.65 (0.18)	-0.96 (-1.46, -0.46) <.001 [-0.45 (-0.70, -0.20)]
Week 9	127	4.6 (2.37)		127	3.6 (2.10)		
Week 9 chg	127	-2.9 (2.32)	-2.76 (0.18)	127	-3.7 (2.03)	-3.71 (0.18)	-0.95 (-1.45, -0.45) <.001 [-0.44 (-0.69, -0.19)]
Week 10	125	4.5 (2.42)		122	3.6 (2.11)		
Week 10 chg	125	-2.9 (2.39)	-2.84 (0.18)	122	-3.7 (1.93)	-3.70 (0.18)	-0.87 (-1.37, -0.36) <.001 [-0.40 (-0.65, -0.15)]
Week 11	128	4.4 (2.41)		126	3.5 (2.15)		
Week 11 chg	128	-3.1 (2.40)	-3.03 (0.18)	126	-3.7 (1.97)	-3.76 (0.18)	-0.73 (-1.23, -0.23) 0.004 [-0.33 (-0.58, -0.09)]
Week 12	123	4.4 (2.36)		121	3.5 (2.08)		
Week 12 chg	123	-3.1 (2.41)	-2.99 (0.18)	121	-3.8 (2.06)	-3.82 (0.18)	-0.83 (-1.33, -0.32) 0.001 [-0.37 (-0.62, -0.12)]
Week 13	116	4.3 (2.38)		120	3.3 (2.06)		
Week 13 chg	116	-3.3 (2.35)	-3.05 (0.18)	120	-4.0 (2.09)	-3.92 (0.18)	-0.87 (-1.38, -0.37) <.001 [-0.39 (-0.65, -0.14)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.1.416.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.11 (0.18)	123	-3.9 (2.12)	-3.85 (0.18)	-0.74 (-1.25, -0.24) [-0.33 (-0.59, -0.08)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.17 (0.18)	123	-4.0 (2.15)	-3.93 (0.18)	-0.76 (-1.26, -0.25) [-0.34 (-0.59, -0.09)]	0.003
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.09 (0.18)	122	-3.9 (2.06)	-3.95 (0.18)	-0.85 (-1.36, -0.35) [-0.39 (-0.64, -0.13)]	<.001
Week 17	121	4.3 (2.46)		121	3.4 (2.13)			
Week 17 chg	121	-3.2 (2.49)	-3.09 (0.18)	121	-3.9 (2.04)	-3.93 (0.18)	-0.84 (-1.35, -0.34) [-0.37 (-0.63, -0.12)]	0.001
Week 18	120	4.4 (2.51)		123	3.3 (2.12)			
Week 18 chg	120	-3.2 (2.46)	-3.04 (0.18)	123	-4.0 (2.11)	-3.96 (0.18)	-0.93 (-1.43, -0.42) [-0.40 (-0.66, -0.15)]	<.001
Week 19	119	4.3 (2.65)		117	3.1 (2.11)			
Week 19 chg	119	-3.3 (2.55)	-3.09 (0.18)	117	-4.2 (2.19)	-4.16 (0.18)	-1.07 (-1.58, -0.57) [-0.45 (-0.71, -0.19)]	<.001
Week 20	120	4.3 (2.68)		118	3.0 (2.02)			
Week 20 chg	120	-3.3 (2.61)	-3.08 (0.18)	118	-4.2 (2.13)	-4.13 (0.18)	-1.05 (-1.56, -0.54) [-0.44 (-0.70, -0.18)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.1.416.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21	118	4.2 (2.59)		115	3.0 (1.94)		
Week 21 chg	118	-3.4 (2.59)	-3.21 (0.18)	115	-4.3 (2.07)	-4.22 (0.18)	-1.01 (-1.52, -0.50) <.001 [-0.43 (-0.69, -0.17)]
Week 22	120	4.2 (2.64)		116	3.0 (1.90)		
Week 22 chg	120	-3.4 (2.64)	-3.23 (0.18)	116	-4.2 (2.06)	-4.23 (0.18)	-1.01 (-1.51, -0.50) <.001 [-0.42 (-0.68, -0.17)]
Week 23	120	4.1 (2.62)		114	3.0 (1.94)		
Week 23 chg	120	-3.5 (2.58)	-3.28 (0.18)	114	-4.3 (2.15)	-4.23 (0.18)	-0.95 (-1.46, -0.44) <.001 [-0.40 (-0.66, -0.14)]
Week 24	120	4.1 (2.52)		112	2.9 (1.92)		
Week 24 chg	120	-3.4 (2.53)	-3.26 (0.18)	112	-4.3 (2.13)	-4.28 (0.18)	-1.02 (-1.53, -0.51) <.001 [-0.43 (-0.69, -0.17)]
Week 25	114	3.8 (2.46)		115	2.9 (1.90)		
Week 25 chg	114	-3.8 (2.50)	-3.46 (0.18)	115	-4.3 (2.08)	-4.34 (0.18)	-0.88 (-1.39, -0.37) <.001 [-0.38 (-0.65, -0.12)]
Week 26	112	3.9 (2.49)		118	3.0 (1.91)		
Week 26 chg	112	-3.6 (2.56)	-3.32 (0.18)	118	-4.3 (2.11)	-4.28 (0.18)	-0.96 (-1.47, -0.45) <.001 [-0.41 (-0.67, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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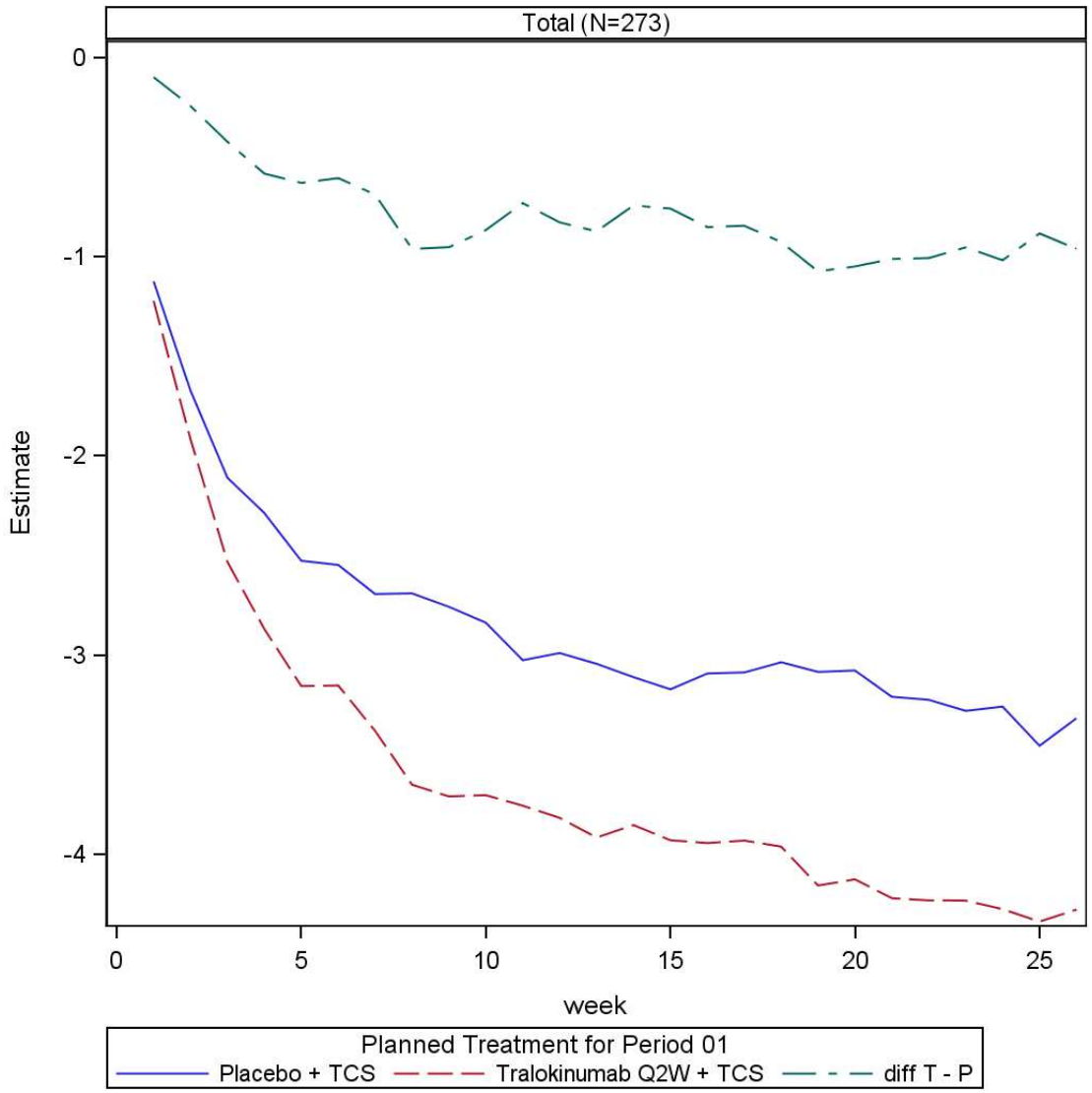
Figure 1.1.416.4.2: Total, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.1.418.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 1		135 5.8 (2.01)			136 5.2 (2.21)		
Week 1 chg		135 -1.1 (1.50)	-1.05 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.10 (-0.61, 0.42) 0.715 [-0.07 (-0.30, 0.17)]
Week 2		134 5.2 (2.29)			132 4.5 (2.45)		
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.19)	-0.18 (-0.70, 0.34) 0.502 [-0.09 (-0.33, 0.15)]
Week 3		133 4.7 (2.36)			131 3.9 (2.35)		
Week 3 chg		133 -2.2 (2.17)	-2.12 (0.19)		131 -2.4 (2.01)	-2.49 (0.19)	-0.37 (-0.89, 0.15) 0.165 [-0.18 (-0.42, 0.07)]
Week 4		130 4.5 (2.48)			133 3.6 (2.39)		
Week 4 chg		130 -2.4 (2.23)	-2.25 (0.19)		133 -2.7 (2.06)	-2.79 (0.19)	-0.54 (-1.06, -0.02) 0.041 [-0.25 (-0.50, -0.01)]
Week 5		131 4.2 (2.55)			129 3.3 (2.42)		
Week 5 chg		131 -2.7 (2.37)	-2.54 (0.19)		129 -3.0 (2.16)	-3.13 (0.19)	-0.59 (-1.11, -0.07) 0.027 [-0.26 (-0.50, -0.01)]
Week 6		130 4.2 (2.52)			129 3.3 (2.42)		
Week 6 chg		130 -2.7 (2.36)	-2.50 (0.19)		129 -3.1 (2.24)	-3.21 (0.19)	-0.71 (-1.23, -0.19) 0.008 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.1.418.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	129 3.9 (2.43)		128	128 3.1 (2.37)		
Week 7 chg	129	129 -3.0 (2.38)	-2.77 (0.19)	128	128 -3.3 (2.28)	-3.41 (0.19)	-0.64 (-1.16, -0.12) 0.016 [-0.27 (-0.52, -0.03)]
Week 8	127	127 3.9 (2.46)		125	125 2.8 (2.29)		
Week 8 chg	127	127 -3.0 (2.32)	-2.75 (0.19)	125	125 -3.6 (2.26)	-3.65 (0.19)	-0.90 (-1.42, -0.38) <.001 [-0.39 (-0.64, -0.14)]
Week 9	127	127 3.8 (2.49)		127	127 2.6 (2.22)		
Week 9 chg	127	127 -3.1 (2.33)	-2.89 (0.19)	127	127 -3.7 (2.23)	-3.84 (0.19)	-0.95 (-1.47, -0.43) <.001 [-0.41 (-0.66, -0.17)]
Week 10	125	125 3.7 (2.54)		122	122 2.7 (2.29)		
Week 10 chg	125	125 -3.2 (2.40)	-3.00 (0.19)	122	122 -3.7 (2.29)	-3.82 (0.19)	-0.82 (-1.34, -0.30) 0.002 [-0.35 (-0.60, -0.10)]
Week 11	128	128 3.6 (2.46)		126	126 2.6 (2.22)		
Week 11 chg	128	128 -3.3 (2.40)	-3.11 (0.19)	126	126 -3.8 (2.26)	-3.90 (0.19)	-0.78 (-1.31, -0.26) 0.003 [-0.34 (-0.58, -0.09)]
Week 12	123	123 3.5 (2.44)		121	121 2.5 (2.21)		
Week 12 chg	123	123 -3.4 (2.45)	-3.14 (0.19)	121	121 -3.8 (2.38)	-4.00 (0.19)	-0.86 (-1.38, -0.33) 0.001 [-0.36 (-0.61, -0.10)]
Week 13	116	116 3.4 (2.40)		120	120 2.3 (2.13)		
Week 13 chg	116	116 -3.6 (2.32)	-3.27 (0.19)	120	120 -3.9 (2.26)	-4.04 (0.19)	-0.77 (-1.30, -0.25) 0.004 [-0.34 (-0.59, -0.08)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.1.418.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	123	3.3 (2.42)		123	2.4 (2.18)		
Week 14 chg	123	-3.5 (2.33)	-3.34 (0.19)	123	-3.9 (2.27)	-4.04 (0.19)	-0.70 (-1.22, -0.18) 0.009 [-0.30 (-0.56, -0.05)]
Week 15	123	3.3 (2.47)		123	2.4 (2.18)		
Week 15 chg	123	-3.7 (2.35)	-3.43 (0.19)	123	-3.9 (2.35)	-4.08 (0.19)	-0.65 (-1.17, -0.12) 0.015 [-0.28 (-0.53, -0.02)]
Week 16	121	3.2 (2.40)		122	2.5 (2.17)		
Week 16 chg	121	-3.7 (2.28)	-3.40 (0.19)	122	-3.9 (2.32)	-4.07 (0.19)	-0.67 (-1.20, -0.15) 0.012 [-0.29 (-0.55, -0.04)]
Week 17	121	3.4 (2.55)		121	2.4 (2.30)		
Week 17 chg	121	-3.6 (2.46)	-3.34 (0.19)	121	-4.0 (2.36)	-4.10 (0.19)	-0.76 (-1.28, -0.23) 0.005 [-0.31 (-0.57, -0.06)]
Week 18	120	3.4 (2.65)		123	2.3 (2.24)		
Week 18 chg	120	-3.6 (2.51)	-3.35 (0.19)	123	-4.0 (2.40)	-4.15 (0.19)	-0.79 (-1.31, -0.27) 0.003 [-0.32 (-0.58, -0.07)]
Week 19	119	3.3 (2.75)		117	2.2 (2.22)		
Week 19 chg	119	-3.7 (2.57)	-3.42 (0.19)	117	-4.1 (2.46)	-4.23 (0.19)	-0.81 (-1.33, -0.28) 0.003 [-0.32 (-0.58, -0.06)]
Week 20	120	3.4 (2.78)		118	2.2 (2.12)		
Week 20 chg	120	-3.6 (2.63)	-3.32 (0.19)	118	-4.1 (2.42)	-4.18 (0.19)	-0.87 (-1.39, -0.34) 0.001 [-0.34 (-0.60, -0.09)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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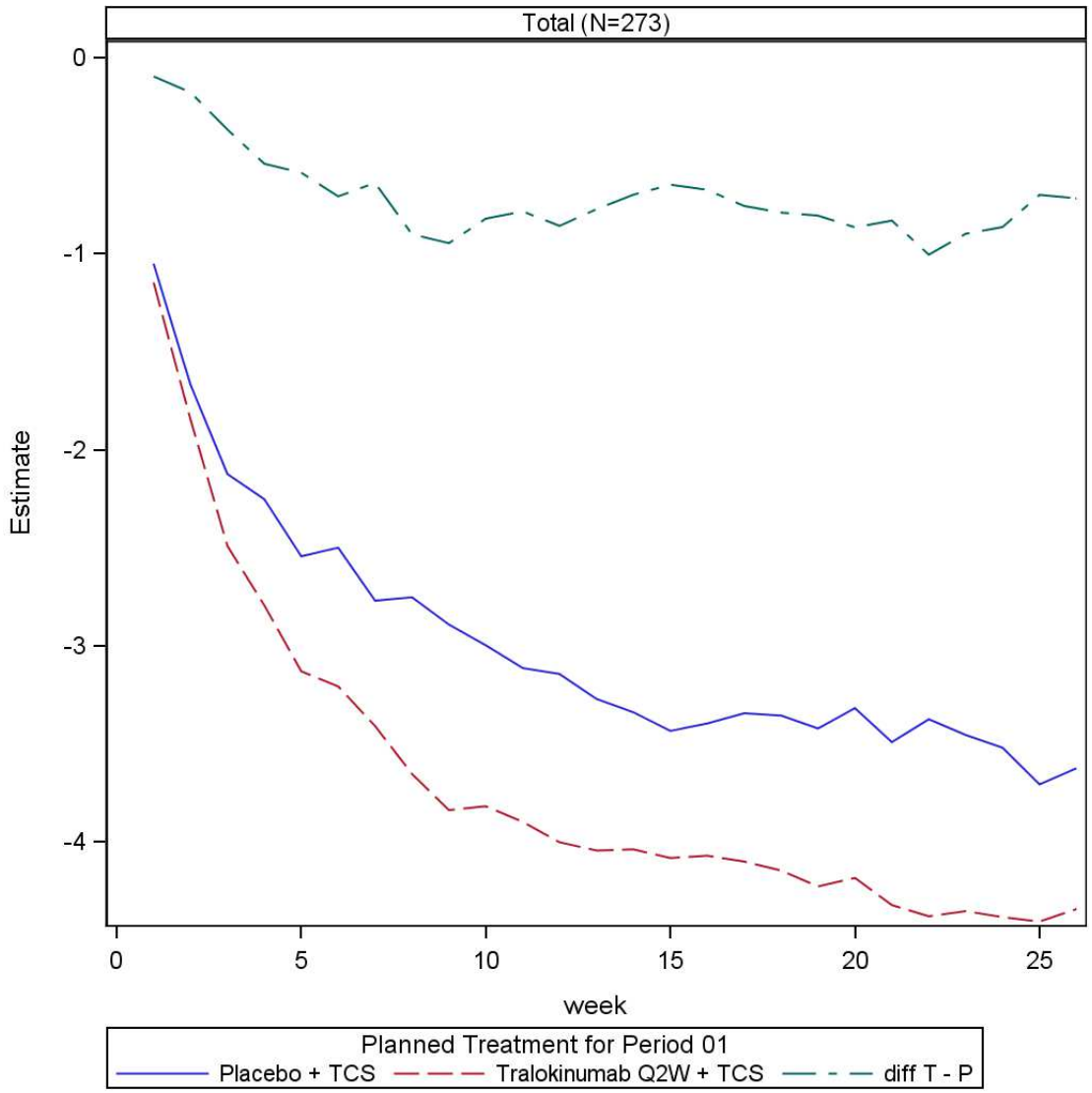
Table 1.1.418.4.1: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21	118	3.2 (2.67)		115	2.1 (2.04)		
Week 21 chg	118	-3.8 (2.62)	-3.49 (0.19)	115	-4.2 (2.37)	-4.32 (0.19)	-0.83 (-1.36, -0.30) 0.002 [-0.33 (-0.59, -0.07)]
Week 22	120	3.3 (2.72)		116	2.0 (1.98)		
Week 22 chg	120	-3.7 (2.65)	-3.37 (0.19)	116	-4.3 (2.35)	-4.38 (0.19)	-1.00 (-1.53, -0.48) <.001 [-0.40 (-0.66, -0.14)]
Week 23	120	3.2 (2.64)		114	2.0 (2.02)		
Week 23 chg	120	-3.7 (2.56)	-3.45 (0.19)	114	-4.2 (2.44)	-4.35 (0.19)	-0.90 (-1.43, -0.37) <.001 [-0.36 (-0.62, -0.10)]
Week 24	120	3.2 (2.59)		112	2.0 (1.91)		
Week 24 chg	120	-3.8 (2.57)	-3.52 (0.19)	112	-4.2 (2.37)	-4.38 (0.19)	-0.86 (-1.39, -0.34) 0.001 [-0.35 (-0.61, -0.09)]
Week 25	114	2.8 (2.49)		115	2.0 (1.97)		
Week 25 chg	114	-4.1 (2.53)	-3.71 (0.19)	115	-4.3 (2.44)	-4.41 (0.19)	-0.70 (-1.23, -0.17) 0.010 [-0.28 (-0.54, -0.02)]
Week 26	112	2.9 (2.50)		118	2.1 (1.98)		
Week 26 chg	112	-4.0 (2.55)	-3.62 (0.19)	118	-4.2 (2.48)	-4.34 (0.19)	-0.72 (-1.25, -0.19) 0.008 [-0.29 (-0.55, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 16:18 LP0162-Payer /p_mmrm3/t_t_total_g18_46_w26.txt

Figure 1.1.418.4.2: Total, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.1.420.4.1: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.24 (1.50)		138 -20.9 (16.72)	-21.09 (1.49)	-3.85 (-8.01, 0.31) 0.070 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.30 (1.51)		137 -30.8 (17.25)	-31.04 (1.50)	-4.74 (-8.92, -0.57) 0.026 [-0.27 (-0.50, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.83 (1.51)		134 -34.3 (17.49)	-34.46 (1.50)	-7.63 (-11.8, -3.43) <.001 [-0.42 (-0.66, -0.17)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.66 (1.51)		130 -36.6 (18.48)	-36.77 (1.51)	-8.11 (-12.3, -3.91) <.001 [-0.42 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.81 (1.51)		130 -38.5 (19.49)	-38.57 (1.51)	-7.76 (-12.0, -3.55) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.59 (1.52)		128 -39.5 (18.74)	-39.57 (1.52)	-7.98 (-12.2, -3.76) <.001 [-0.42 (-0.66, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.420.4.1: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 36.0 (19.61)			127 28.3 (17.87)		
Week 14 chg		126 -34.8 (20.31)	-34.25 (1.53)		127 -41.8 (20.11)	-41.39 (1.52)	-7.14 (-11.4, -2.91) <.001 [-0.35 (-0.60, -0.11)]
Week 16		124 36.3 (18.78)			123 27.0 (16.90)		
Week 16 chg		124 -34.7 (19.94)	-33.90 (1.53)		123 -43.3 (19.46)	-42.70 (1.53)	-8.80 (-13.0, -4.55) <.001 [-0.45 (-0.70, -0.19)]
Week 18		116 36.8 (19.98)			115 25.1 (15.97)		
Week 18 chg		116 -34.1 (20.70)	-33.27 (1.55)		115 -44.8 (19.27)	-43.62 (1.55)	-10.36 (-14.7, -6.05) <.001 [-0.52 (-0.78, -0.26)]
Week 20		107 35.7 (19.63)			117 25.6 (16.83)		
Week 20 chg		107 -35.6 (20.01)	-34.07 (1.57)		117 -44.9 (18.80)	-43.48 (1.54)	-9.41 (-13.7, -5.08) <.001 [-0.49 (-0.75, -0.22)]
Week 22		112 35.6 (20.27)			114 23.3 (14.77)		
Week 22 chg		112 -35.5 (20.64)	-34.08 (1.56)		114 -46.8 (19.03)	-45.23 (1.55)	-11.15 (-15.5, -6.83) <.001 [-0.56 (-0.83, -0.30)]
Week 24		112 34.6 (19.86)			117 23.3 (15.61)		
Week 24 chg		112 -36.5 (20.30)	-34.56 (1.56)		117 -46.9 (18.55)	-45.65 (1.54)	-11.09 (-15.4, -6.78) <.001 [-0.57 (-0.84, -0.31)]
Week 26		118 33.1 (18.32)			125 23.8 (16.51)		
Week 26 chg		118 -38.1 (19.21)	-36.22 (1.54)		125 -46.3 (19.60)	-45.94 (1.52)	-9.72 (-14.0, -5.46) <.001 [-0.50 (-0.76, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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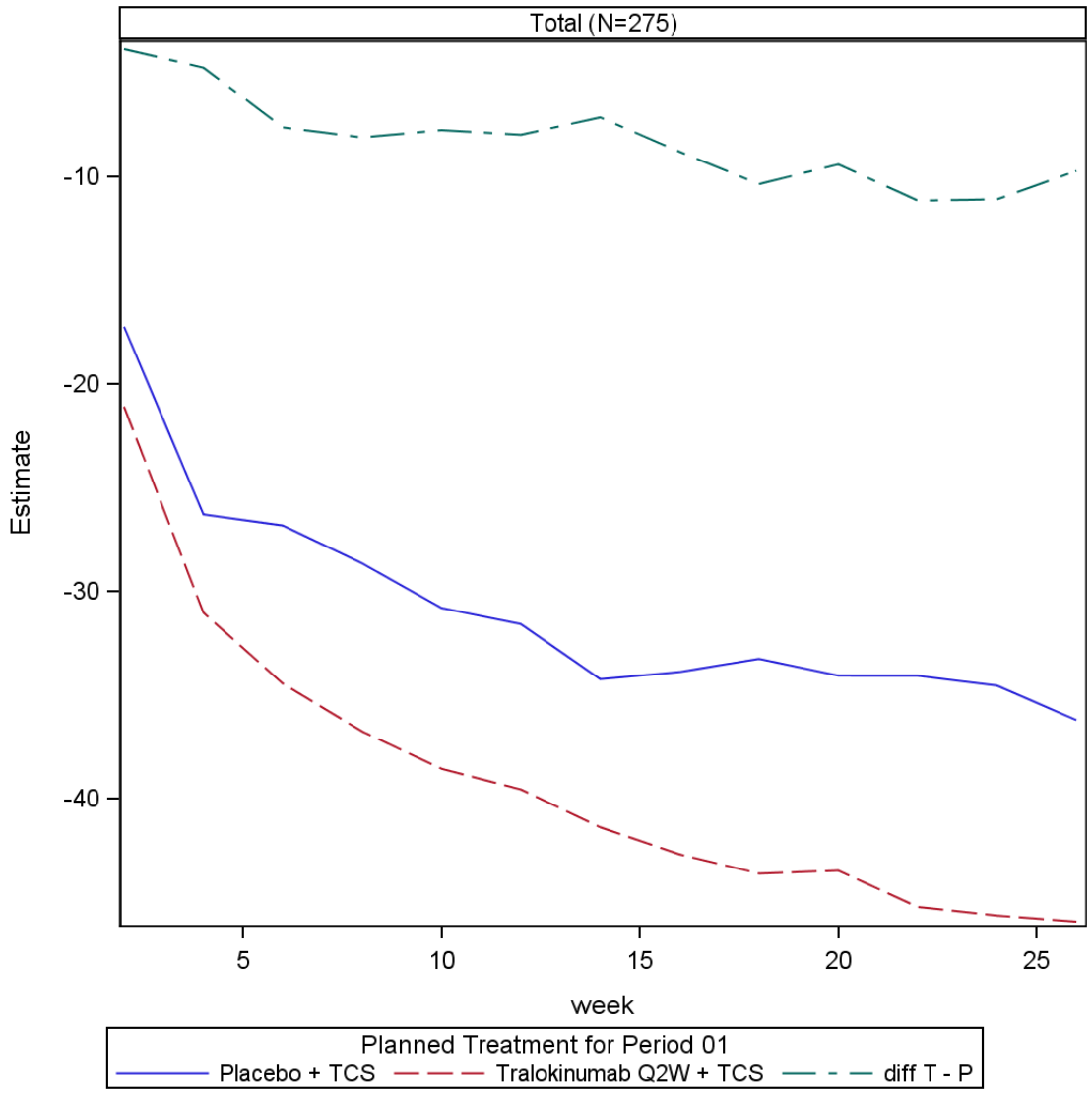
Figure 1.1.420.4.2: Total, change in SCORAD, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.1.422.4.1: Total, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score											
Total											
Baseline	137	134	16.4 (6.33)			138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)				132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.13 (0.44)			132	-7.5 (5.92)	-7.54 (0.44)		-0.41 (-1.63, 0.81) 0.508 [-0.07 (-0.31, 0.17)]
Week 4		130	7.8 (6.27)				135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.30 (0.44)			135	-9.0 (6.32)	-9.13 (0.44)		-0.82 (-2.04, 0.40) 0.185 [-0.13 (-0.37, 0.11)]
Week 6		123	7.3 (6.07)				126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.60 (0.45)			126	-10.0 (6.75)	-9.85 (0.44)		-1.25 (-2.48, -0.01) 0.048 [-0.18 (-0.43, 0.07)]
Week 8		127	6.9 (5.70)				128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.94 (0.44)			128	-10.6 (6.29)	-10.36 (0.44)		-1.41 (-2.64, -0.19) 0.024 [-0.22 (-0.46, 0.03)]
Week 12		123	6.8 (5.89)				124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.29 (0.45)			124	-10.6 (5.77)	-10.55 (0.44)		-1.26 (-2.50, -0.02) 0.046 [-0.19 (-0.44, 0.06)]
Week 16		120	6.5 (5.63)				118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.45)			118	-11.0 (5.99)	-11.14 (0.45)		-1.46 (-2.71, -0.22) 0.022 [-0.23 (-0.49, 0.02)]

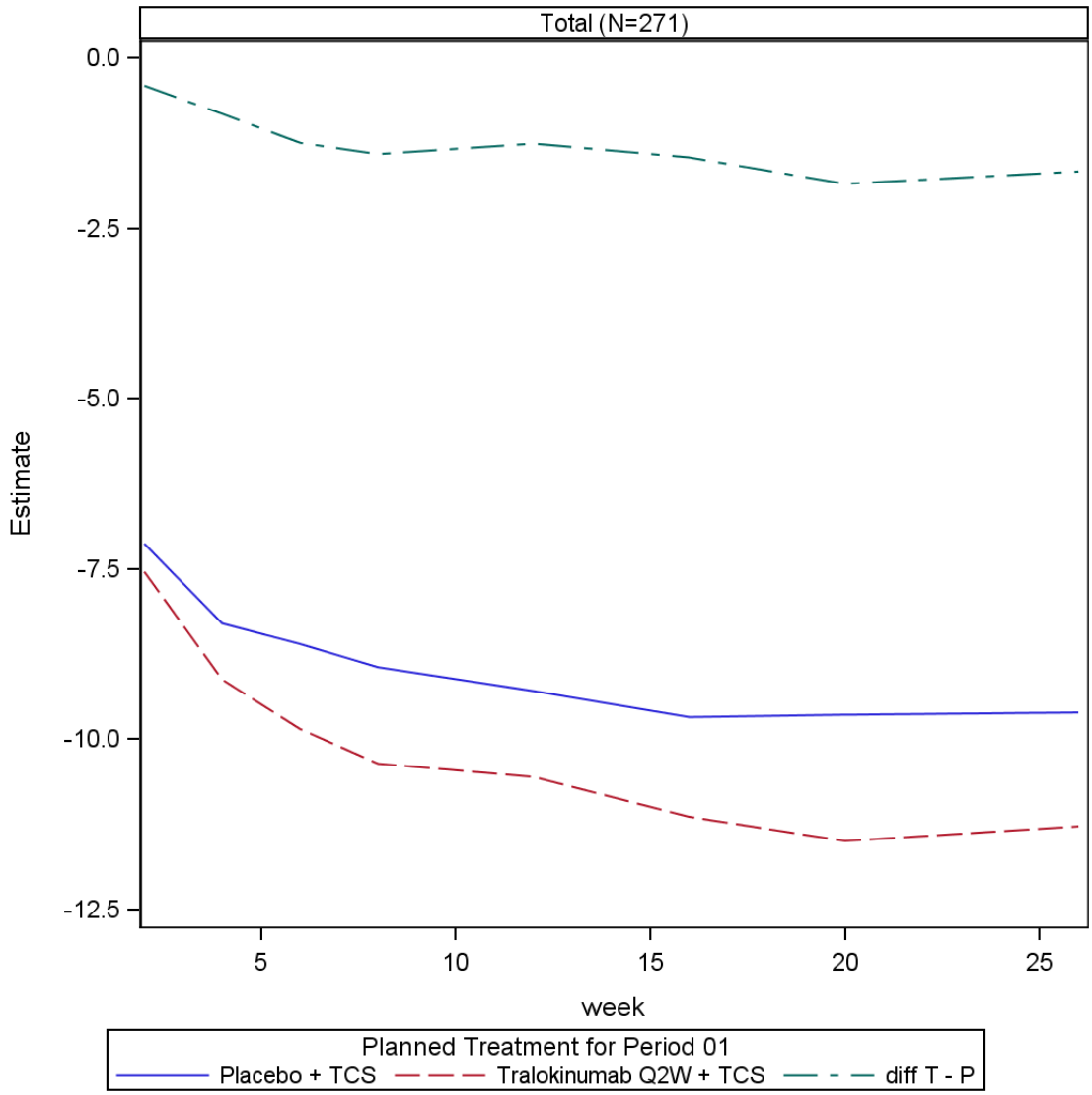
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.422.4.1: Total, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 20	102	6.2 (5.67)		111	4.1 (3.92)		
Week 20 chg	102	-9.9 (7.06)	-9.64 (0.46)	111	-11.4 (5.58)	-11.49 (0.45)	-1.85 (-3.13, -0.57) 0.005 [-0.29 (-0.56, -0.02)]
Week 26	110	6.3 (5.26)		116	4.3 (4.31)		
Week 26 chg	110	-10.4 (6.56)	-9.61 (0.46)	116	-11.1 (6.17)	-11.28 (0.45)	-1.67 (-2.93, -0.41) 0.010 [-0.26 (-0.52, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.422.4.2: Total, change in DLQI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.1.423.4.1: Total, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 2		130 15.1 (6.91)			130 13.5 (6.31)			
Week 2 chg		130 -5.9 (6.29)	-5.97 (0.55)		130 -7.7 (5.43)	-7.67 (0.55)	-1.71 (-3.23, -0.18) [-0.29 (-0.53, -0.05)]	0.029
Week 4		130 13.8 (7.45)			133 11.6 (6.30)			
Week 4 chg		130 -7.1 (7.56)	-7.11 (0.55)		133 -9.7 (6.02)	-9.53 (0.55)	-2.42 (-3.94, -0.89) [-0.35 (-0.60, -0.11)]	0.002
Week 6		123 13.5 (7.81)			124 10.9 (5.95)			
Week 6 chg		123 -7.2 (8.29)	-7.29 (0.56)		124 -10.6 (6.27)	-10.35 (0.56)	-3.07 (-4.61, -1.52) [-0.42 (-0.67, -0.17)]	<.001
Week 8		127 13.1 (7.02)			126 9.9 (5.79)			
Week 8 chg		127 -7.6 (7.95)	-7.70 (0.55)		126 -11.5 (6.10)	-11.16 (0.55)	-3.46 (-5.00, -1.92) [-0.49 (-0.74, -0.24)]	<.001
Week 12		123 13.0 (7.39)			122 9.2 (5.72)			
Week 12 chg		123 -8.0 (8.26)	-7.91 (0.56)		122 -12.4 (6.20)	-11.78 (0.56)	-3.88 (-5.43, -2.33) [-0.53 (-0.79, -0.28)]	<.001
Week 16		120 13.0 (7.69)			116 9.1 (5.58)			
Week 16 chg		120 -8.0 (8.09)	-8.08 (0.56)		116 -12.2 (6.39)	-11.81 (0.56)	-3.73 (-5.30, -2.17) [-0.51 (-0.77, -0.25)]	<.001

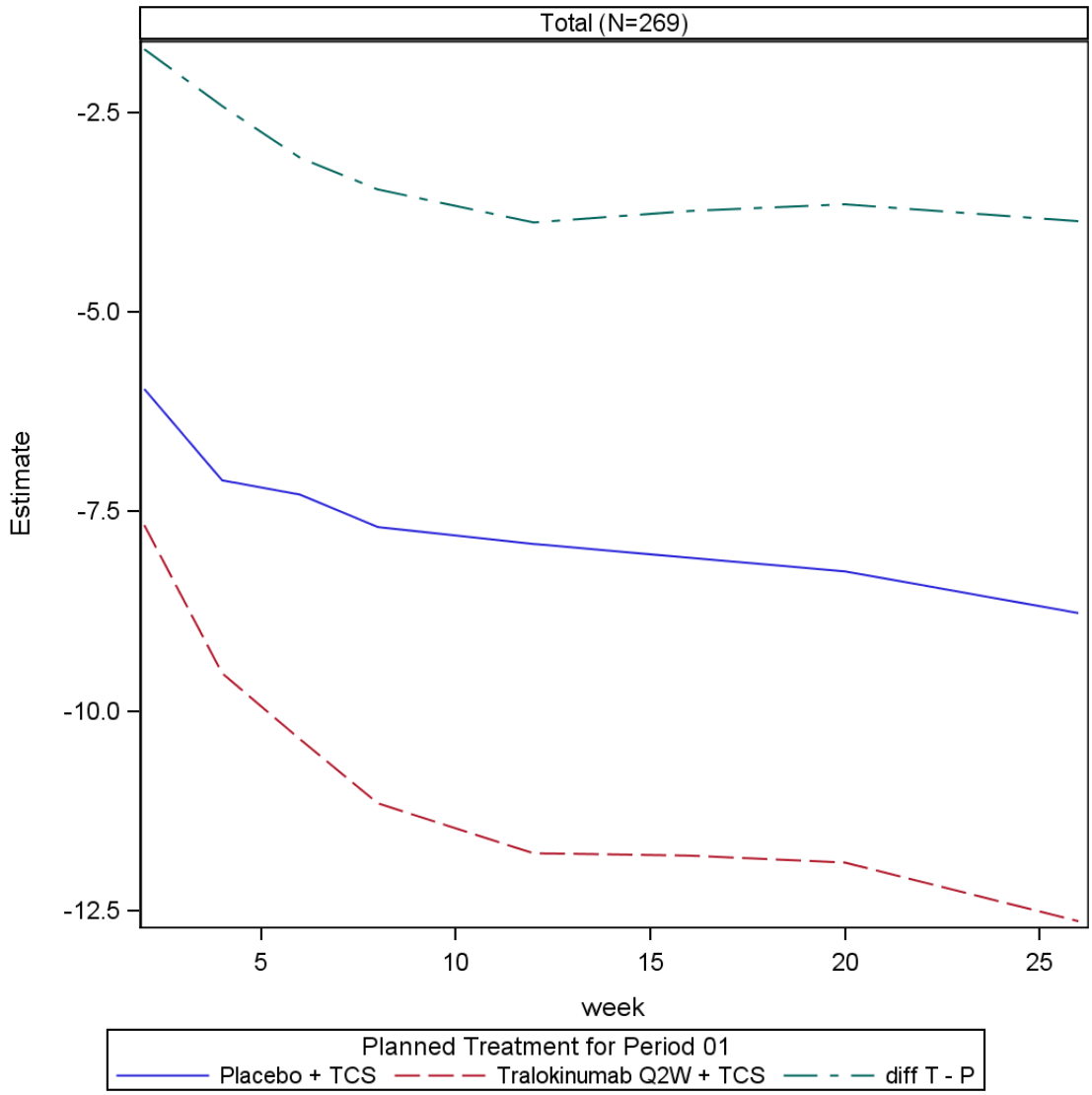
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.423.4.1: Total, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	12.3 (7.64)		109	9.0 (5.60)			
Week 20 chg	102	-8.3 (7.60)	-8.25 (0.58)	109	-12.2 (6.08)	-11.90 (0.57)	-3.65 (-5.25, -2.05) [-0.53 (-0.81, -0.26)]	<.001
Week 26	110	11.8 (7.82)		114	8.2 (5.65)			
Week 26 chg	110	-8.9 (8.23)	-8.77 (0.57)	114	-12.8 (6.59)	-12.64 (0.57)	-3.86 (-5.44, -2.28) [-0.52 (-0.79, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.1.423.4.2: Total, change in POEM, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.1.428.4.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.41 (0.22)		138 -2.8 (2.87)	-2.87 (0.22)	-0.45 (-1.08, 0.17) 0.153 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.23 (0.23)		137 -3.8 (2.99)	-3.80 (0.22)	-0.58 (-1.20, 0.05) 0.071 [-0.18 (-0.42, 0.06)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.15 (0.23)		134 -4.1 (2.81)	-4.07 (0.23)	-0.92 (-1.55, -0.29) 0.004 [-0.30 (-0.54, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.50 (0.23)		130 -4.4 (2.91)	-4.34 (0.23)	-0.84 (-1.47, -0.21) 0.009 [-0.27 (-0.51, -0.03)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.65 (0.23)		130 -4.5 (2.93)	-4.46 (0.23)	-0.81 (-1.44, -0.18) 0.012 [-0.26 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.73 (0.23)		128 -4.6 (2.96)	-4.55 (0.23)	-0.83 (-1.46, -0.19) 0.011 [-0.26 (-0.51, -0.01)]

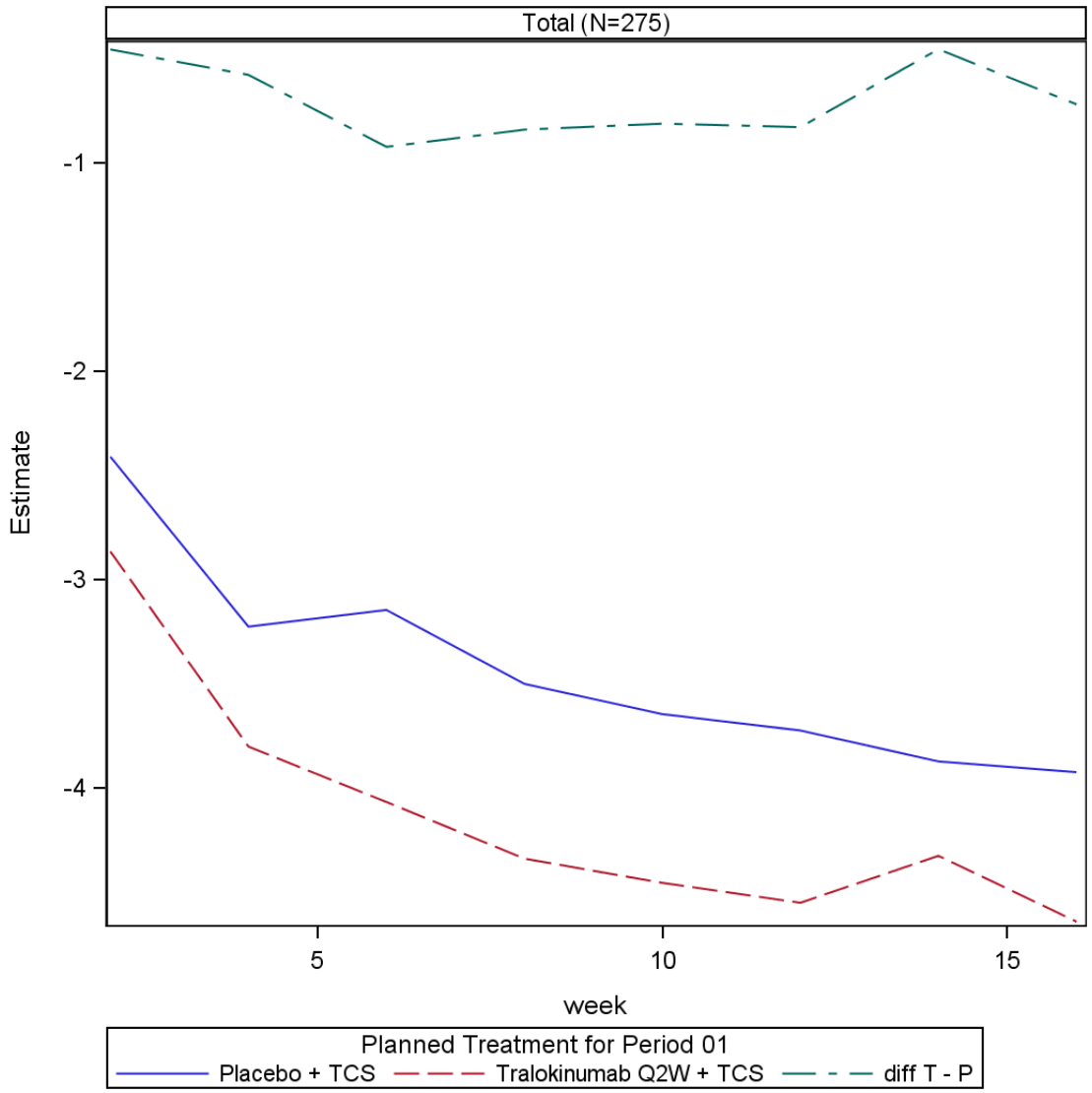
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.1.428.4.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	126	2.8 (2.94)		127	2.3 (2.60)			
Week 14 chg	126	-4.0 (3.48)	-3.88 (0.23)	127	-4.4 (3.07)	-4.33 (0.23)	-0.45 (-1.09, 0.18) [-0.14 (-0.38, 0.11)]	0.161
Week 16	124	2.7 (2.77)		123	1.9 (2.39)			
Week 16 chg	124	-4.1 (3.25)	-3.93 (0.23)	123	-4.7 (2.92)	-4.64 (0.23)	-0.72 (-1.36, -0.08) [-0.23 (-0.48, 0.02)]	0.027

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.1.428.4.2: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16



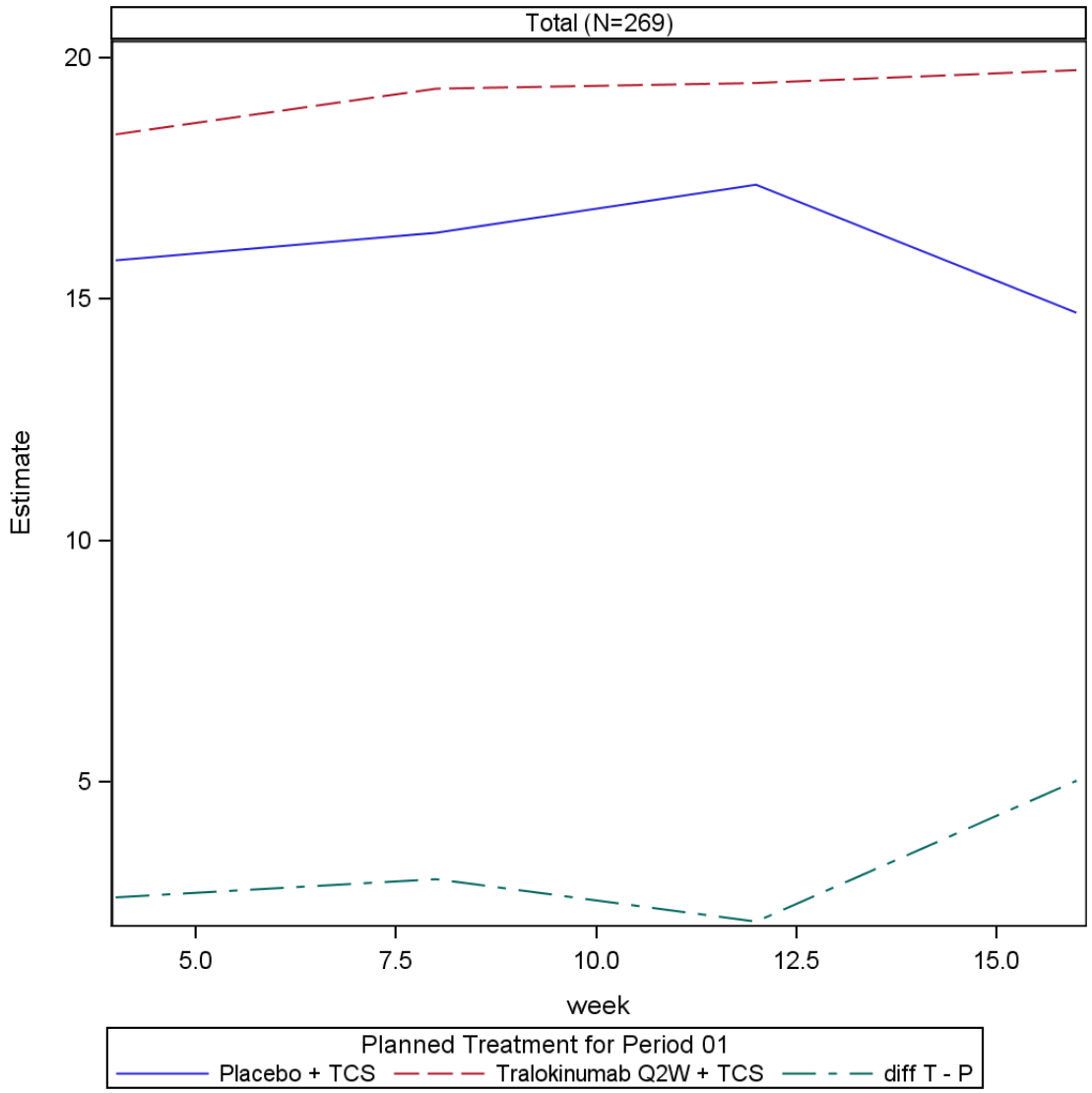
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Region + Baseline IGA. In case of no post-baseline assessments 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 Prior CSA use, 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 1.1.429.4.1: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.80 (1.50)		133	17.3 (19.49)	18.41 (1.49)	2.61 (-1.55, 6.77) 0.219 [0.13 (-0.12, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.37 (1.51)		126	18.4 (21.17)	19.36 (1.51)	2.99 (-1.23, 7.20) 0.165 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.37 (1.53)		122	18.7 (21.48)	19.47 (1.53)	2.11 (-2.15, 6.37) 0.332 [0.09 (-0.16, 0.35)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.72 (1.54)		116	17.7 (22.49)	19.74 (1.55)	5.02 (0.71, 9.33) 0.022 [0.20 (-0.05, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.1.429.4.2: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16



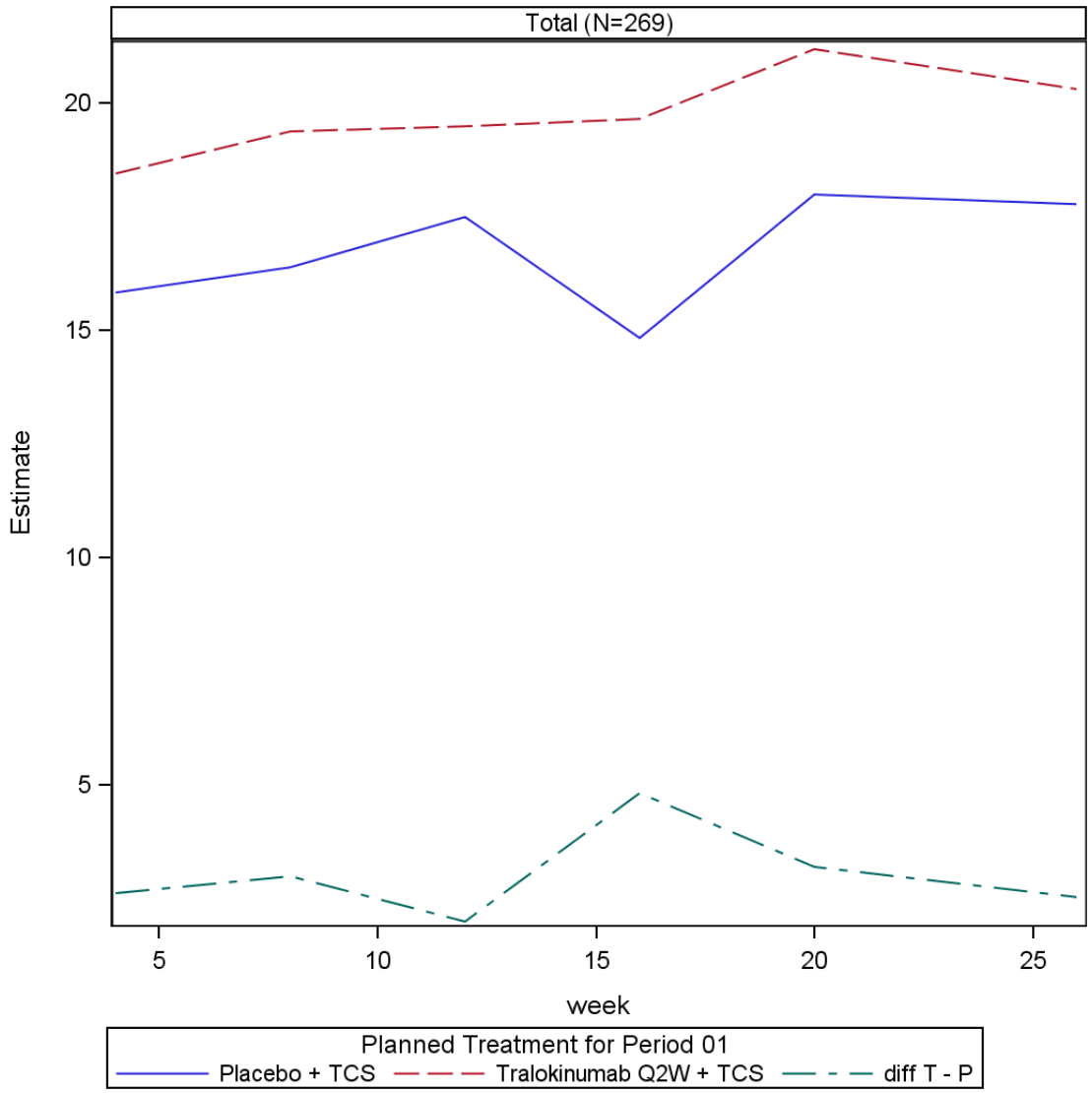
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Region + Baseline IGA. In case of no post-baseline assessments 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 Prior CSA use, 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 1.1.430.4.1: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.83 (1.52)		133	17.3 (19.49)	18.45 (1.50)	2.62 (-1.59, 6.82) 0.222 [0.13 (-0.11, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.39 (1.53)		126	18.4 (21.17)	19.38 (1.53)	2.99 (-1.26, 7.24) 0.168 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.49 (1.54)		122	18.7 (21.48)	19.49 (1.54)	1.99 (-2.30, 6.29) 0.362 [0.09 (-0.16, 0.34)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.83 (1.55)		116	17.7 (22.49)	19.65 (1.57)	4.82 (0.48, 9.16) 0.030 [0.19 (-0.06, 0.45)]
Week 20		103	72.7 (20.07)			108	77.3 (14.52)		
Week 20 chg		103	19.3 (25.56)	17.99 (1.61)		108	21.6 (20.57)	21.18 (1.59)	3.20 (-1.26, 7.65) 0.159 [0.14 (-0.13, 0.41)]
Week 26		113	72.4 (20.84)			116	76.4 (17.02)		
Week 26 chg		113	20.5 (25.83)	17.77 (1.58)		116	19.5 (21.18)	20.31 (1.56)	2.53 (-1.84, 6.90) 0.256 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.1.430.4.2: Total, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.1.431.4.1: Total, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 26		117 2.9 (2.55)			122 2.1 (2.00)		
Week 26 chg		116 -4.0 (2.53)	-3.74 (0.21)		121 -4.1 (2.47)	-4.34 (0.20)	-0.60 (-1.17, -0.03) 0.040 [-0.24 (-0.50, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.434.4.1: Total, SCORAD 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	21 (15.2)	11.7 (5.02;18.46)	4.3 (1.66;10.96)	5.0 (1.80;13.99)	0.0009	
Placebo + TCS	137	5 (3.6)					

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. Treatment policy estimand: Missing values at Week 26 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

Table 1.1.436.4.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.39 (0.22)		138 -2.8 (2.87)	-2.85 (0.22)	-0.46 (-1.08, 0.15) 0.141 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.20 (0.23)		137 -3.8 (2.99)	-3.79 (0.23)	-0.59 (-1.23, 0.05) 0.072 [-0.19 (-0.43, 0.05)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.13 (0.23)		134 -4.1 (2.81)	-4.06 (0.23)	-0.93 (-1.58, -0.29) 0.005 [-0.30 (-0.55, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.47 (0.22)		130 -4.4 (2.91)	-4.31 (0.22)	-0.84 (-1.45, -0.22) 0.008 [-0.27 (-0.51, -0.03)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.61 (0.23)		130 -4.5 (2.93)	-4.42 (0.23)	-0.81 (-1.45, -0.17) 0.014 [-0.25 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.70 (0.22)		128 -4.6 (2.96)	-4.53 (0.22)	-0.83 (-1.45, -0.20) 0.009 [-0.26 (-0.51, -0.01)]

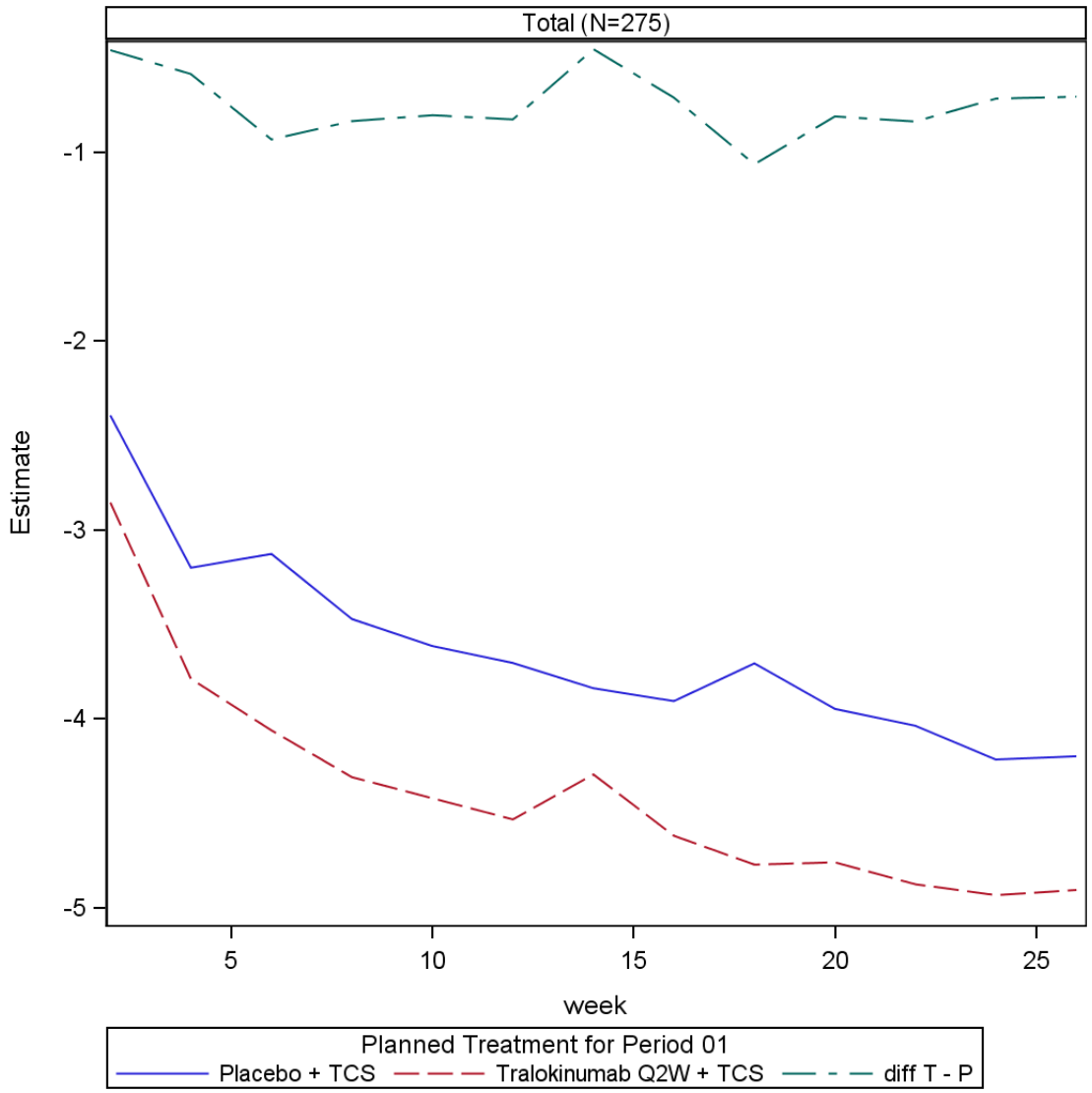
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.436.4.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	2.8 (2.94)		127	2.3 (2.60)		
Week 14 chg	126	-4.0 (3.48)	-3.84 (0.24)	127	-4.4 (3.07)	-4.29 (0.24)	-0.46 (-1.12, 0.21) 0.178 [-0.14 (-0.39, 0.11)]
Week 16	124	2.7 (2.77)		123	1.9 (2.39)		
Week 16 chg	124	-4.1 (3.25)	-3.91 (0.22)	123	-4.7 (2.92)	-4.62 (0.22)	-0.71 (-1.33, -0.09) 0.025 [-0.23 (-0.48, 0.02)]
Week 18	116	2.9 (2.83)		115	1.7 (2.27)		
Week 18 chg	116	-3.9 (3.35)	-3.71 (0.23)	115	-4.8 (2.93)	-4.77 (0.23)	-1.06 (-1.69, -0.43) 0.001 [-0.34 (-0.60, -0.08)]
Week 20	107	2.6 (2.71)		117	1.8 (2.37)		
Week 20 chg	107	-4.1 (3.17)	-3.95 (0.23)	117	-4.8 (2.97)	-4.76 (0.22)	-0.81 (-1.44, -0.18) 0.012 [-0.26 (-0.53, -0.00)]
Week 22	112	2.5 (2.71)		114	1.5 (2.00)		
Week 22 chg	112	-4.2 (3.34)	-4.04 (0.22)	114	-5.0 (2.85)	-4.88 (0.22)	-0.84 (-1.46, -0.21) 0.009 [-0.27 (-0.53, -0.01)]
Week 24	112	2.3 (2.55)		117	1.5 (2.05)		
Week 24 chg	112	-4.4 (3.18)	-4.22 (0.21)	117	-5.1 (2.80)	-4.93 (0.21)	-0.72 (-1.31, -0.12) 0.018 [-0.24 (-0.50, 0.02)]
Week 26	118	2.4 (2.70)		125	1.6 (2.07)		
Week 26 chg	118	-4.4 (3.11)	-4.20 (0.21)	125	-5.0 (2.80)	-4.91 (0.21)	-0.71 (-1.30, -0.12) 0.019 [-0.24 (-0.49, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.436.4.2: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.437.4.1: Total, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 26		121 2.5 (2.71)			127 1.6 (2.07)		
Week 26 chg		121 -4.4 (3.09)	-4.30 (0.21)		127 -5.0 (2.78)	-5.09 (0.21)	-0.78 (-1.37, -0.20) 0.009 [-0.27 (-0.52, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.438.4.1: Total, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 26		121 33.4 (18.31)			127 24.1 (16.65)		
Week 26 chg		121 -37.9 (19.30)	-37.26 (1.53)		127 -45.9 (19.70)	-46.62 (1.50)	-9.36 (-13.6, -5.13) <.001 [-0.48 (-0.73, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.439.4.1: Total, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)							
Total							
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)		
Week 26		117 3.9 (2.53)			122 3.0 (1.94)		
Week 26 chg		116 -3.6 (2.55)	-3.47 (0.20)		121 -4.2 (2.13)	-4.31 (0.20)	-0.84 (-1.41, -0.28) 0.004 [-0.36 (-0.62, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.440.4.1: Total, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 26		115 11.9 (7.89)			119 8.4 (5.90)			
Week 26 chg		113 -8.7 (8.23)	-8.90 (0.62)		116 -12.7 (6.64)	-12.63 (0.62)	-3.73 (-5.46, -2.00) [-0.50 (-0.76, -0.24)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.442.4.1: Total, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 26		115 6.2 (5.20)			119 4.4 (4.42)		
Week 26 chg		113 -10.3 (6.57)	-10.01 (0.42)		118 -11.2 (6.17)	-11.51 (0.41)	-1.50 (-2.66, -0.34) 0.011 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.443.4.1: Total, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 26		121 9.0 (10.05)			127 5.8 (7.95)		
Week 26 chg		121 -25.4 (13.63)	-24.33 (0.78)		127 -26.3 (12.87)	-27.34 (0.76)	-3.02 (-5.16, -0.87) 0.006 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.444.3.1: Total, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	126	126 30.4 (12.78)		252	252 28.8 (11.97)		
Week 16		123 14.1 (14.89)			241 8.1 (9.15)		
Week 16 chg		123 -16.0 (14.04)	-15.43 (0.94)		241 -20.7 (12.33)	-20.93 (0.67)	-5.50 (-7.79, -3.22) <.001 [-0.43 (-0.64, -0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.1.445.4.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss										
Total										
Baseline	137	137	6.7 (2.21)		138	138	6.7 (2.36)			
Week 2		137	4.3 (2.75)			138	3.8 (2.71)			
Week 2 chg		137	-2.4 (2.99)	-2.39 (0.22)		138	-2.8 (2.87)	-2.85 (0.22)	-0.46 (-1.07, 0.15) [-0.16 (-0.39, 0.08)]	0.140
Week 4		134	3.4 (2.75)			137	2.9 (2.68)			
Week 4 chg		134	-3.3 (3.29)	-3.20 (0.22)		137	-3.8 (2.99)	-3.79 (0.22)	-0.58 (-1.20, 0.03) [-0.19 (-0.42, 0.05)]	0.062
Week 6		132	3.5 (2.88)			134	2.6 (2.58)			
Week 6 chg		132	-3.2 (3.30)	-3.13 (0.22)		134	-4.1 (2.81)	-4.06 (0.22)	-0.93 (-1.54, -0.31) [-0.30 (-0.54, -0.06)]	0.003
Week 8		133	3.2 (2.69)			130	2.3 (2.47)			
Week 8 chg		133	-3.6 (3.29)	-3.47 (0.22)		130	-4.4 (2.91)	-4.33 (0.22)	-0.85 (-1.47, -0.24) [-0.27 (-0.52, -0.03)]	0.007
Week 10		131	3.0 (2.78)			130	2.2 (2.56)			
Week 10 chg		131	-3.8 (3.38)	-3.62 (0.22)		130	-4.5 (2.93)	-4.44 (0.22)	-0.82 (-1.43, -0.20) [-0.26 (-0.50, -0.01)]	0.009
Week 12		128	2.9 (2.68)			128	2.1 (2.48)			
Week 12 chg		128	-3.9 (3.37)	-3.70 (0.22)		128	-4.6 (2.96)	-4.53 (0.22)	-0.83 (-1.45, -0.21) [-0.26 (-0.51, -0.02)]	0.008

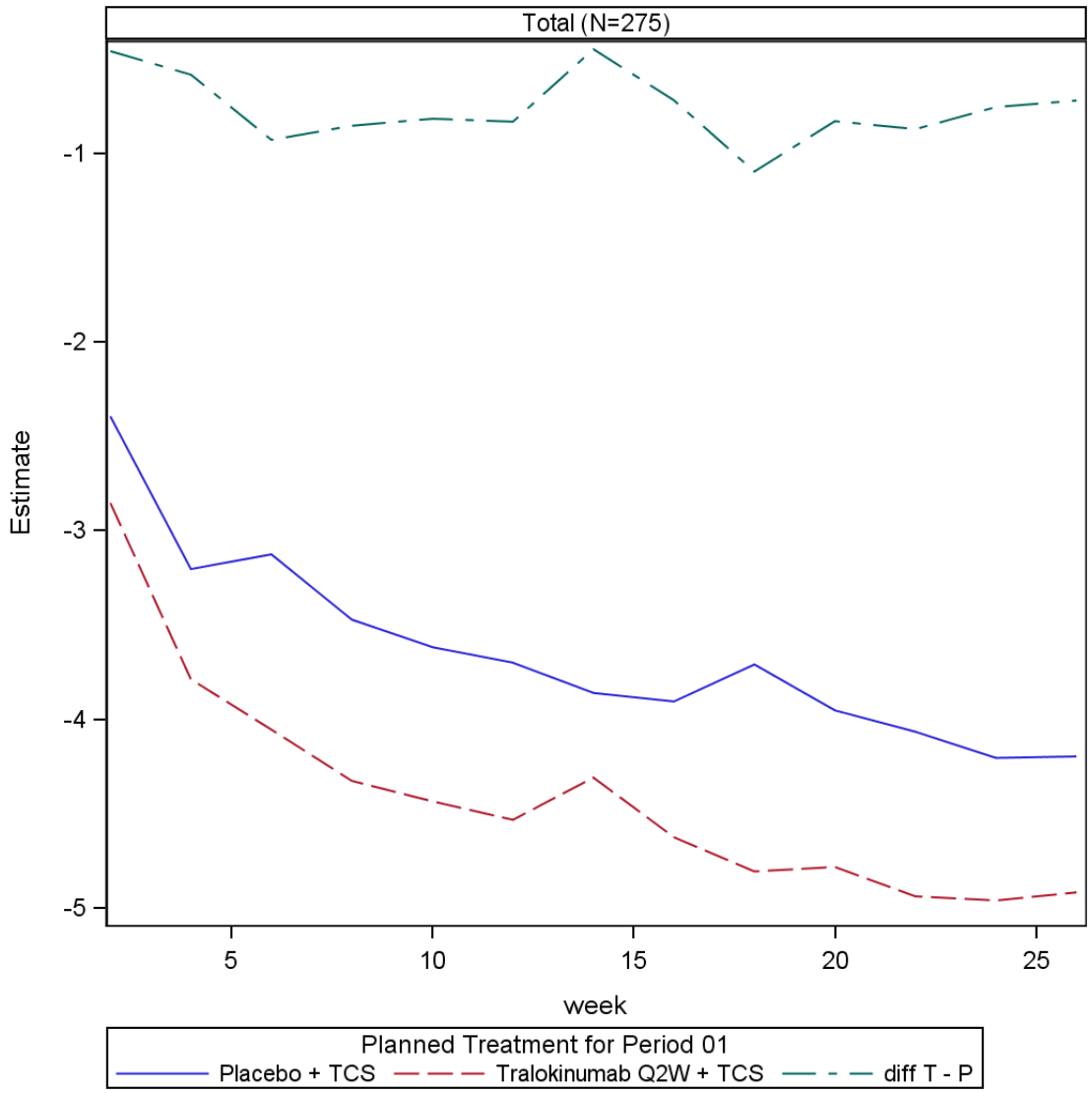
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.445.4.1: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	2.8 (2.94)		127	2.3 (2.60)		
Week 14 chg	126	-4.0 (3.48)	-3.86 (0.22)	127	-4.4 (3.07)	-4.31 (0.22)	-0.45 (-1.07, 0.17) 0.156 [-0.14 (-0.38, 0.11)]
Week 16	124	2.7 (2.77)		123	1.9 (2.39)		
Week 16 chg	124	-4.1 (3.25)	-3.91 (0.22)	123	-4.7 (2.92)	-4.63 (0.22)	-0.72 (-1.34, -0.10) 0.024 [-0.23 (-0.48, 0.02)]
Week 18	116	2.9 (2.83)		115	1.7 (2.27)		
Week 18 chg	116	-3.9 (3.35)	-3.71 (0.23)	115	-4.8 (2.93)	-4.81 (0.23)	-1.10 (-1.73, -0.47) <.001 [-0.35 (-0.61, -0.09)]
Week 20	107	2.6 (2.71)		117	1.8 (2.37)		
Week 20 chg	107	-4.1 (3.17)	-3.95 (0.23)	117	-4.8 (2.97)	-4.78 (0.23)	-0.83 (-1.46, -0.20) 0.010 [-0.27 (-0.53, -0.01)]
Week 22	112	2.5 (2.71)		114	1.5 (2.00)		
Week 22 chg	112	-4.2 (3.34)	-4.07 (0.23)	114	-5.0 (2.85)	-4.94 (0.23)	-0.87 (-1.51, -0.24) 0.007 [-0.28 (-0.54, -0.02)]
Week 24	112	2.3 (2.55)		117	1.5 (2.05)		
Week 24 chg	112	-4.4 (3.18)	-4.21 (0.23)	117	-5.1 (2.80)	-4.96 (0.23)	-0.76 (-1.39, -0.12) 0.019 [-0.25 (-0.51, 0.01)]
Week 26	118	2.4 (2.70)		125	1.6 (2.07)		
Week 26 chg	118	-4.4 (3.11)	-4.20 (0.23)	125	-5.0 (2.80)	-4.92 (0.22)	-0.72 (-1.35, -0.10) 0.024 [-0.24 (-0.50, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.445.4.2: Total, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.446.4.1: Total, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score									
Total									
Baseline	137	137	33.8 (13.46)		138	138	32.1 (11.53)		
Week 16		124	10.5 (11.42)			123	6.4 (7.63)		
Week 16 chg		124	-23.8 (14.93)	-22.89 (0.84)		123	-25.9 (12.78)	-26.75 (0.84)	-3.86 (-6.21, -1.51) 0.001 [-0.28 (-0.53, -0.03)]

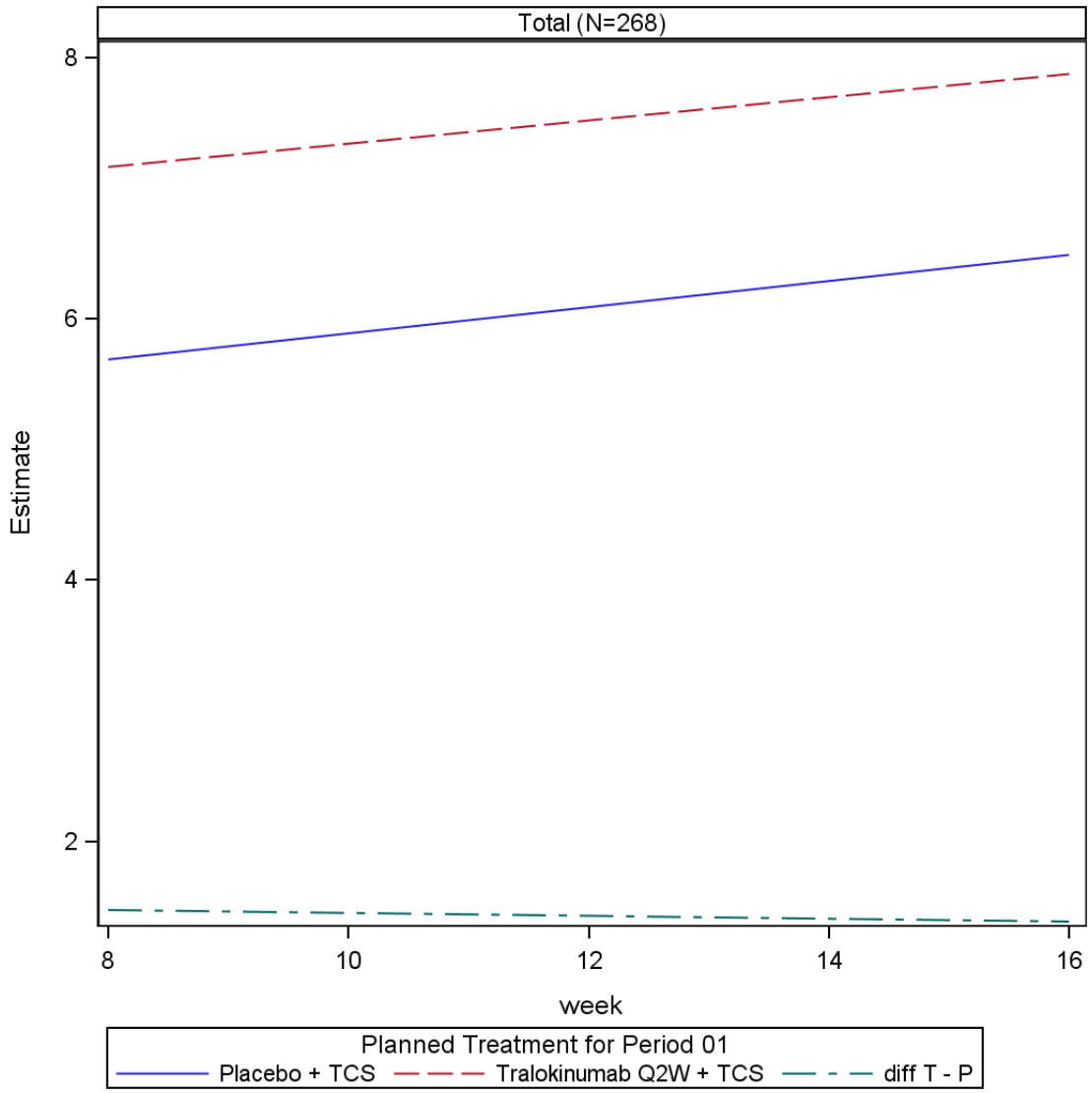
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.463.4.1: Total, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary							
Total							
Baseline	137	134 44.5 (8.19)		138	134 44.5 (7.83)		
Week 8		129 50.3 (7.06)			129 51.7 (7.07)		
Week 8 chg		129 5.6 (7.75)	5.69 (0.56)		129 7.4 (7.27)	7.16 (0.56)	1.47 (-0.08, 3.03) 0.063 [0.20 (-0.05, 0.44)]
Week 16		119 50.9 (7.78)			113 52.9 (6.85)		
Week 16 chg		119 6.8 (8.15)	6.49 (0.57)		113 8.0 (7.67)	7.87 (0.58)	1.39 (-0.22, 2.99) 0.090 [0.17 (-0.08, 0.43)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.1.463.4.2: Total, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16



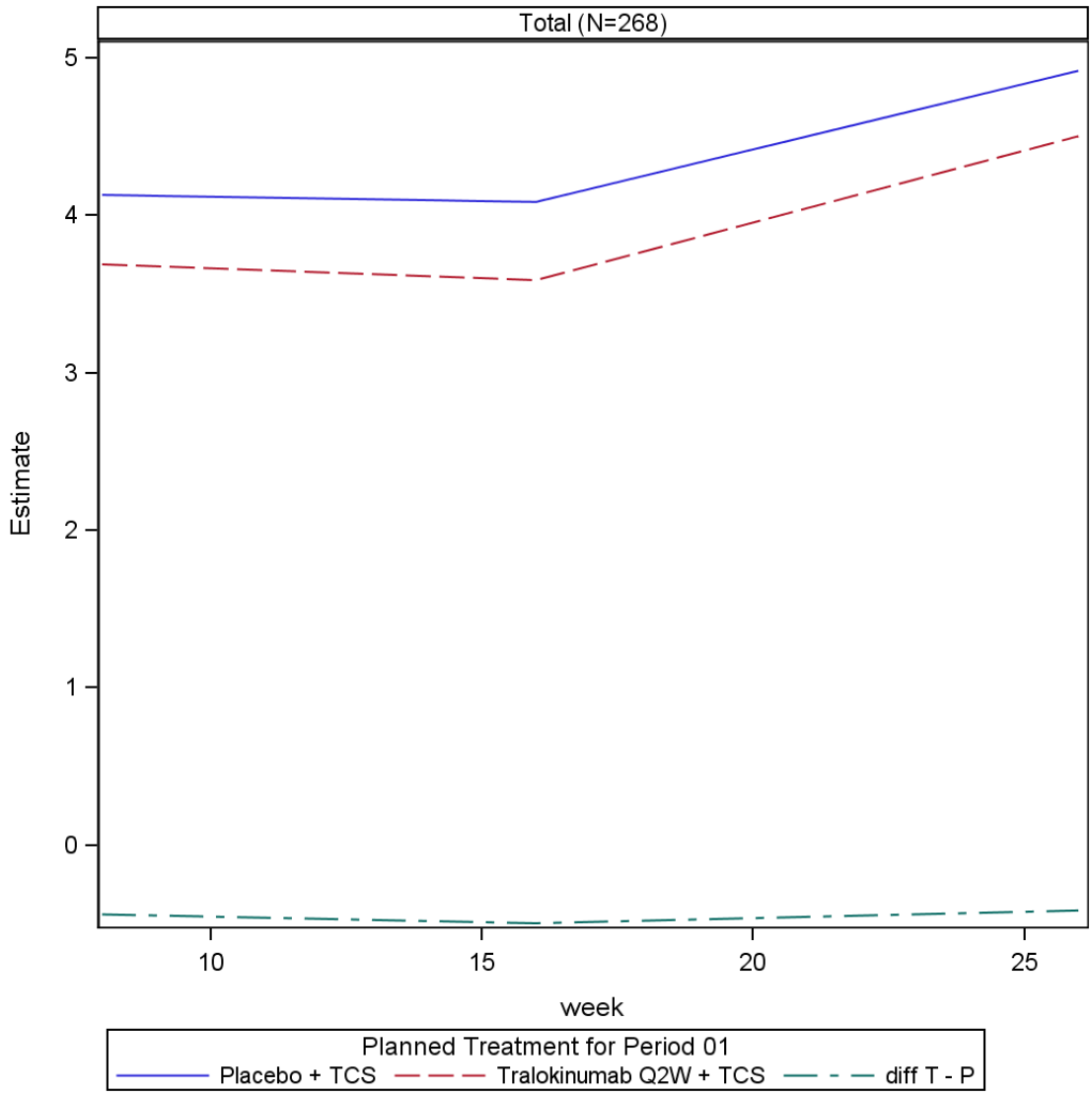
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.1.464.4.1: Total, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary									
Total									
Baseline	137	134	44.9 (11.42)		138	134	46.3 (9.74)		
Week 8		129	49.6 (10.25)			129	49.7 (9.51)		
Week 8 chg		129	4.4 (7.37)	4.13 (0.64)		129	3.7 (8.69)	3.69 (0.63)	-0.44 (-2.21, 1.33) 0.625 [-0.05 (-0.30, 0.19)]
Week 16		119	49.5 (10.11)			113	49.9 (9.68)		
Week 16 chg		119	4.4 (8.65)	4.08 (0.65)		113	3.4 (8.59)	3.59 (0.66)	-0.50 (-2.32, 1.33) 0.594 [-0.06 (-0.32, 0.20)]
Week 26		110	50.4 (9.75)			112	51.4 (7.72)		
Week 26 chg		110	5.5 (8.68)	4.92 (0.67)		112	4.6 (8.26)	4.50 (0.66)	-0.42 (-2.27, 1.44) 0.660 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.1.464.4.2: Total, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26



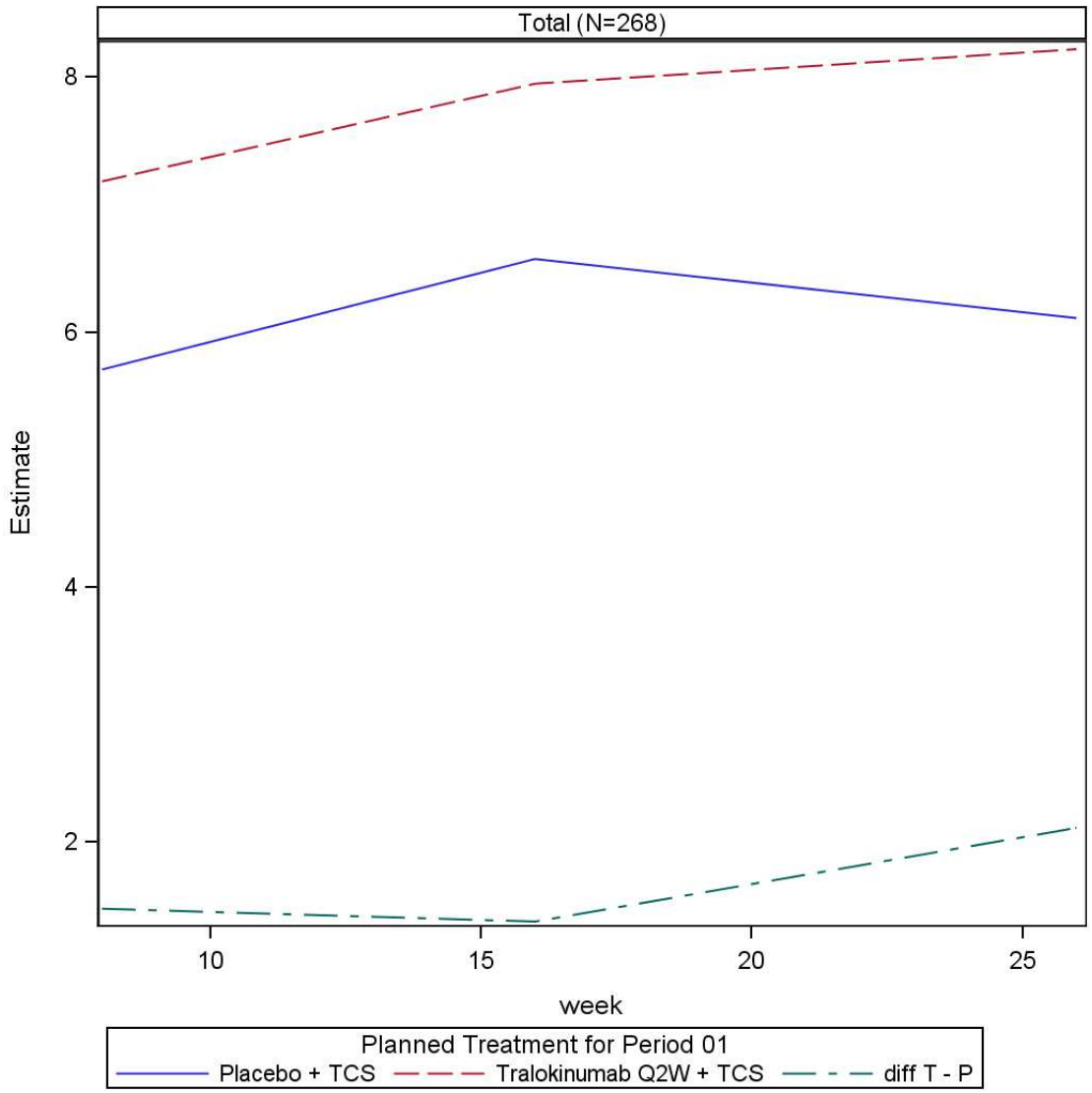
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.1.465.4.1: Total, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary							
Total							
Baseline	137	134 44.5 (8.19)		138	134 44.5 (7.83)		
Week 8		129 50.3 (7.06)			129 51.7 (7.07)		
Week 8 chg		129 5.6 (7.75)	5.70 (0.56)		129 7.4 (7.27)	7.18 (0.56)	1.48 (-0.09, 3.04) 0.064 [0.20 (-0.05, 0.44)]
Week 16		119 50.9 (7.78)			113 52.9 (6.85)		
Week 16 chg		119 6.8 (8.15)	6.57 (0.57)		113 8.0 (7.67)	7.95 (0.58)	1.37 (-0.23, 2.98) 0.093 [0.17 (-0.08, 0.43)]
Week 26		110 50.7 (7.62)			112 52.9 (7.40)		
Week 26 chg		110 6.9 (8.19)	6.11 (0.59)		112 8.2 (7.71)	8.22 (0.58)	2.11 (0.48, 3.74) 0.011 [0.27 (0.00, 0.53)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.1.465.4.2: Total, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26



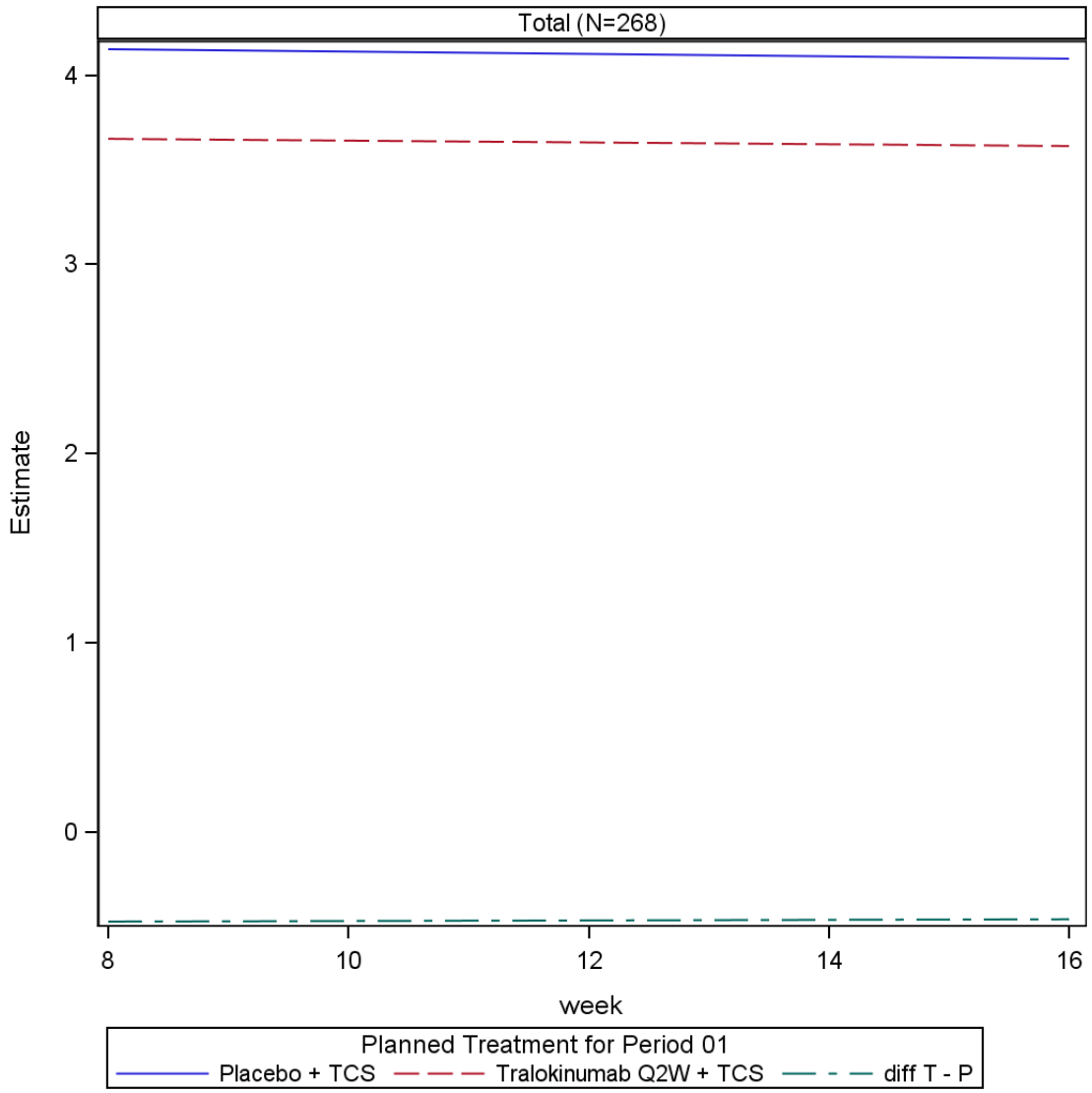
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.1.466.4.1: Total, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary							
Total							
Baseline	137	134 44.9 (11.42)		138	134 46.3 (9.74)		
Week 8		129 49.6 (10.25)			129 49.7 (9.51)		
Week 8 chg		129 4.4 (7.37)	4.14 (0.65)		129 3.7 (8.69)	3.66 (0.65)	-0.47 (-2.28, 1.34) 0.607 [-0.06 (-0.30, 0.19)]
Week 16		119 49.5 (10.11)			113 49.9 (9.68)		
Week 16 chg		119 4.4 (8.65)	4.09 (0.67)		113 3.4 (8.59)	3.63 (0.68)	-0.46 (-2.34, 1.42) 0.629 [-0.05 (-0.31, 0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.1.466.4.2: Total, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16



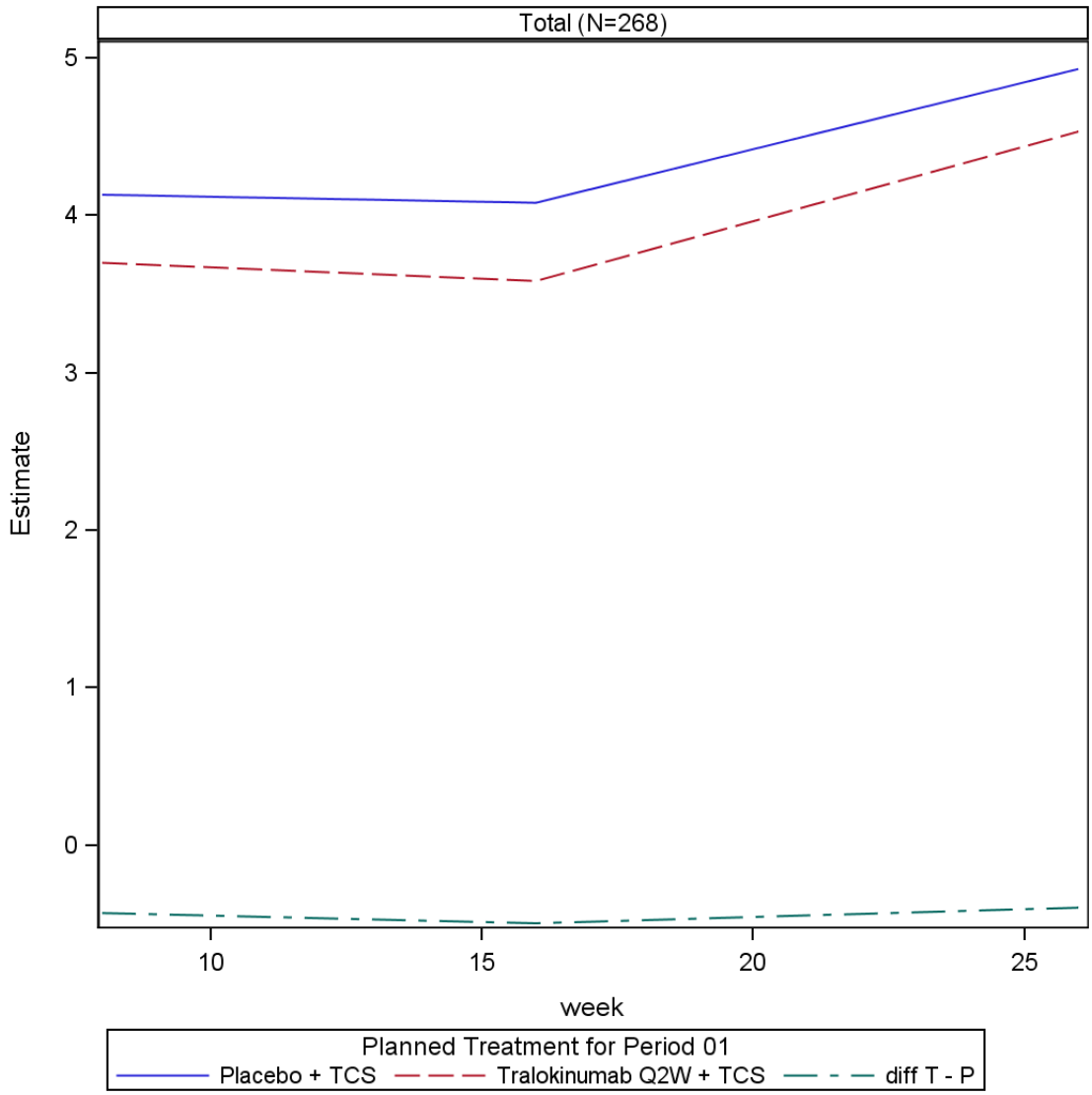
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.1.467.4.1: Total, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary									
Total									
Baseline	137	134	44.9 (11.42)		138	134	46.3 (9.74)		
Week 8		129	49.6 (10.25)			129	49.7 (9.51)		
Week 8 chg		129	4.4 (7.37)	4.13 (0.63)		129	3.7 (8.69)	3.70 (0.63)	-0.43 (-2.18, 1.32) 0.627 [-0.05 (-0.30, 0.19)]
Week 16		119	49.5 (10.11)			113	49.9 (9.68)		
Week 16 chg		119	4.4 (8.65)	4.08 (0.68)		113	3.4 (8.59)	3.58 (0.69)	-0.50 (-2.42, 1.42) 0.611 [-0.06 (-0.32, 0.20)]
Week 26		110	50.4 (9.75)			112	51.4 (7.72)		
Week 26 chg		110	5.5 (8.68)	4.93 (0.64)		112	4.6 (8.26)	4.53 (0.64)	-0.40 (-2.18, 1.38) 0.661 [-0.05 (-0.31, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.467.4.2: Total, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26



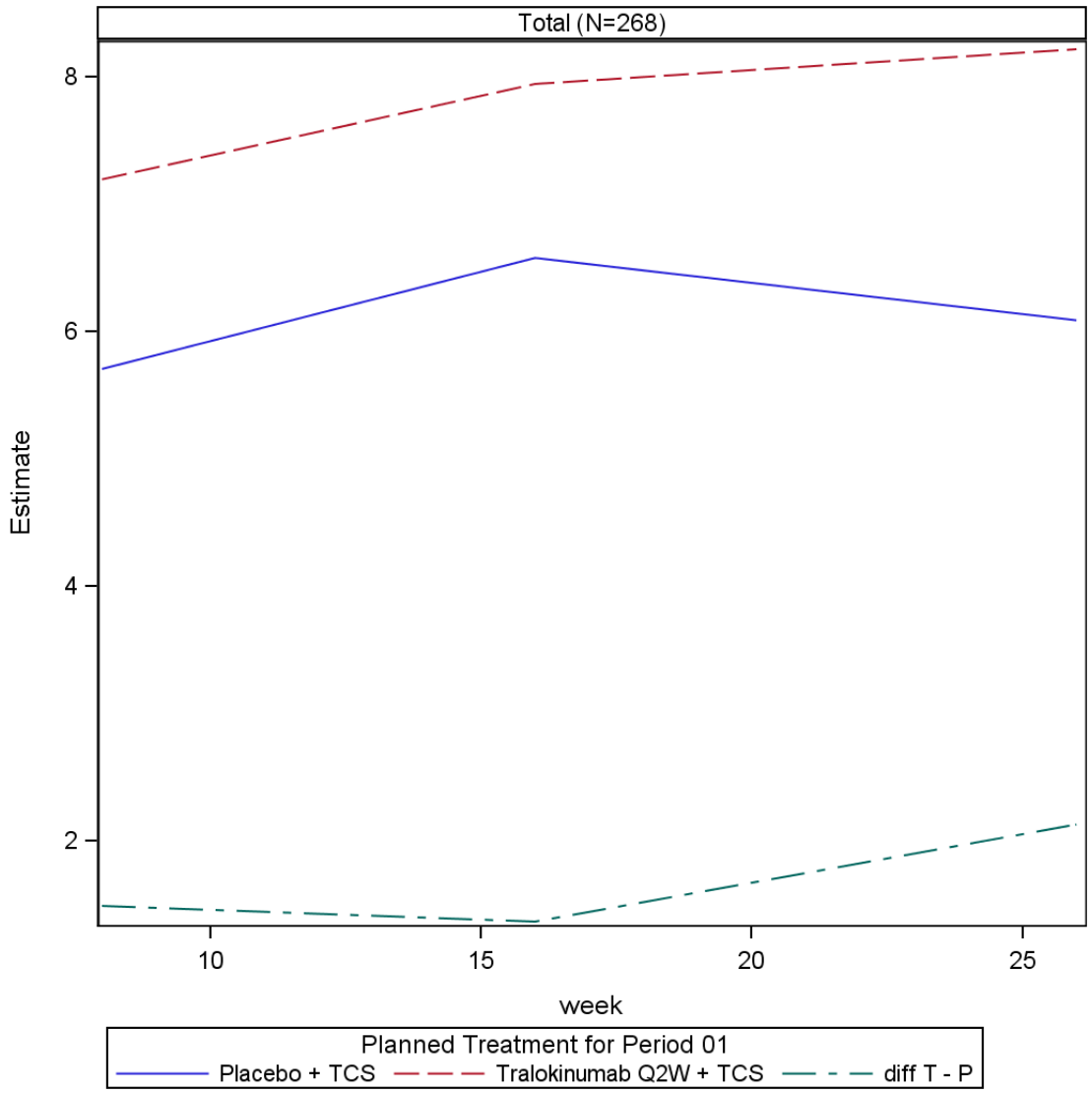
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.468.4.1: Total, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary							
Total							
Baseline	137	134 44.5 (8.19)		138	134 44.5 (7.83)		
Week 8		129 50.3 (7.06)			129 51.7 (7.07)		
Week 8 chg		129 5.6 (7.75)	5.70 (0.54)		129 7.4 (7.27)	7.19 (0.54)	1.49 (-0.03, 3.00) 0.054 [0.20 (-0.05, 0.44)]
Week 16		119 50.9 (7.78)			113 52.9 (6.85)		
Week 16 chg		119 6.8 (8.15)	6.57 (0.58)		113 8.0 (7.67)	7.94 (0.59)	1.37 (-0.26, 2.99) 0.100 [0.17 (-0.09, 0.43)]
Week 26		110 50.7 (7.62)			112 52.9 (7.40)		
Week 26 chg		110 6.9 (8.19)	6.09 (0.60)		112 8.2 (7.71)	8.21 (0.60)	2.13 (0.46, 3.80) 0.013 [0.27 (0.00, 0.53)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.1.468.4.2: Total, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.1.469.4.1: Total, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary							
Total							
Baseline	137	134 44.9 (11.42)		138	134 46.3 (9.74)		
Week 26		115 50.7 (9.70)			118 51.1 (7.88)		
Week 26 chg		113 5.6 (8.87)	5.14 (0.66)		114 4.4 (8.31)	4.80 (0.66)	-0.34 (-2.18, 1.50) 0.715 [-0.04 (-0.30, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.470.4.1: Total, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary							
Total							
Baseline	137	134 44.5 (8.19)		138	134 44.5 (7.83)		
Week 26		115 50.9 (7.60)			118 52.8 (7.38)		
Week 26 chg		113 6.8 (8.15)	6.63 (0.62)		114 8.4 (7.77)	8.47 (0.62)	1.84 (0.11, 3.56) 0.037 [0.23 (-0.03, 0.49)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.471.4.1: Total, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary									
Total									
Baseline	137	134	44.9 (11.42)		138	134	46.3 (9.74)		
Week 16		121	49.5 (10.08)			117	50.1 (9.57)		
Week 16 chg		119	4.4 (8.65)	4.12 (0.70)		113	3.4 (8.59)	3.70 (0.72)	-0.42 (-2.41, 1.56) 0.675 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.472.4.1: Total, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary									
Total									
Baseline	137	134	44.5 (8.19)		138	134	44.5 (7.83)		
Week 16		121	51.0 (7.75)			117	52.8 (6.79)		
Week 16 chg		119	6.8 (8.15)	6.60 (0.60)		113	8.0 (7.67)	8.20 (0.61)	1.60 (-0.09, 3.28) 0.063 [0.20 (-0.06, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction:
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.1.701.3.1: Total, Any TEAE, LP0162-1339, Adverse events subgroup tests by PT

SOC Preferred term Subgroup	Test for inter-action	CMH RR p-value	95%CI	OR 95%CI	RD 95%CI	Placebo + TCS n	(%)	E	Tralokinumab Q2W + TCS n	(%)	E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504

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 1.1.701.4.1: Total, Any TEAE, LP0162-1346, Adverse events subgroup tests by PT

SOC Preferred term Subgroup	Test for inter-action	CMH				Placebo + TCS			Tralokinumab Q2W + TCS		
		p-value	RR 95%CI	OR 95%CI	RD 95%CI	n	(%)	E	n	(%)	E
Analysis set N, Exposure(years) Total						137	65.4		138	65.4	
Any system organ class Any preferred term Total		0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385

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 1.1.702.3.1: Total, Any drug-related TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.0023	1.58 (1.16, 2.16)	2.11 (1.30, 3.42)	15.7 (6.11, 25.2)	34	(27.0)	61	108	(42.9)	232

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 1.1.702.4.1: Total, Any drug-related TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.2852	1.19 (0.86, 1.65)	1.32 (0.80, 2.17)	6.1 (-5.0, 17.3)	43	(31.4)	94	52	(37.7)	105

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 1.1.703.3.1: Total, Any TEAE causing permanent discontinuation, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1 (0.8)		1	6 (2.4)		8

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 1.1.703.4.1: Total, Any TEAE causing permanent discontinuation, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3	(2.2)	4	1	(0.7)	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. TEAE: Treatment emergent adverse events

Table 1.1.704.3.1: Total, Any mild TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.1405	1.14 (0.95, 1.36)	1.41 (0.89, 2.23)	7.5 (-2.5, 17.5)	69	(54.8)	132	157	(62.3)	384

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 1.1.704.4.1: Total, Any mild TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.9615	1.00 (0.87, 1.16)	1.01 (0.60, 1.71)	0.3 (-10, 10.9)	98	(71.5)	293	99	(71.7)	300

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 1.1.705.3.1: Total, Any moderate TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.6376	1.09 (0.75, 1.59)	1.13 (0.68, 1.85)	2.2 (-7.0, 11.4)	30	(23.8)	42	66	(26.2)	113

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 1.1.705.4.1: Total, Any moderate TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.0876	0.75 (0.53, 1.05)	0.65 (0.39, 1.07)	-9.8 (-21, 1.39)	53	(38.7)	121	40	(29.0)	82

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 1.1.706.3.1: Total, Any severe TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.1738	0.50 (0.18, 1.39)	0.48 (0.16, 1.41)	-2.8 (-7.3, 1.68)	7	(5.6)	10	7	(2.8)	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 1.1.706.4.1: Total, Any severe TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.1235	0.37 (0.10, 1.38)	0.36 (0.09, 1.39)	-3.7 (-8.3, 0.97)	8	(5.8)	9	3	(2.2)	3

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 1.1.707.3.1: Total, Death, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	

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.

Table 1.1.707.4.1: Total, Death, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	

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.

Table 1.1.708.3.1: Total, Any TE SAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4	(3.2)	4	2	(0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.1.708.4.1: Total, Any TE SAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5	(3.6)	9	1	(0.7)	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. TE SAE: Treatment emergent serious adverse events

Table 1.1.709.3.1: Total, Any drug-related TE SAE, LP0162-1339, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	ChiSq / p-value	RR / 95%CI	CMH OR / 95%CI	RD / 95%CI	Placebo + TCS n	(%)	E	Tralokinumab Q2W + TCS n	(%)	E
Total					126	37.9		252	75.0	

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 1.1.709.4.1: Total, Any drug-related TE SAE, LP0162-1346, Adverse events subgroup tests by PT

SOC Preferred term Subgroup	Test for inter-action	CMH RR p-value	95%CI	OR 95%CI	RD 95%CI	Placebo + TCS n	(%)	E	Tralokinumab Q2W + TCS n	(%)	E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2	(1.5)	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 1.1.710.3.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	

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 1.1.710.4.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2	(1.5)	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 1.1.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504

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 1.1.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, Adverse events subgroup tests by PT

SOC Preferred term Subgroup	Test for inter-action	CMH RR p-value	95%CI	OR 95%CI	RD 95%CI	Placebo + TCS n	(%)	E	Tralokinumab Q2W + TCS n	(%)	E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385

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 1.1.712.3.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4	(3.2)	4	2	(0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.1.712.4.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1346, Adverse events subgroup tests by PT

SOC Preferred term Subgroup	Test for inter-action	CMH RR p-value	95%CI	OR 95%CI	RD 95%CI	Placebo + TCS n	(%)	E	Tralokinumab Q2W + TCS n	(%)	E
Analysis set N, Exposure(years) Total						137	65.4		138	65.4	
Any system organ class Any preferred term Total		0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5	(3.6)	9	1	(0.7)	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. TE SAE: Treatment emergent serious adverse events

Table 1.1.713.3.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1	(0.8)	1	6	(2.4)	8

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 1.1.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3	(2.2)	4	1	(0.7)	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. TE SAE: Treatment emergent serious adverse events

Table 1.1.714.3.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for interaction p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set										
N, Exposure(years)										
Total					126	37.9		252	75.0	
Any system organ class										
Any preferred term										
Total	0.0185	2.40 (1.10, 5.22)	2.71 (1.15, 6.37)	7.8 (2.10, 13.5)	7	(5.6)	7	34	(13.5)	39

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

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Table 1.1.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.0780	2.14 (0.90, 5.07)	2.28 (0.90, 5.77)	5.8 (-.58, 12.2)	7	(5.1)	9	15	(10.9)	17

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 1.1.715.3.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	

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

17FEB21 16:53 LP0162-Payer /p_aetest/T_t_total_t15_39.txt

Table 1.1.715.4.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	

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 1.1.716.3.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1	(0.8)	1	1	(0.4)	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 1.1.716.4.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	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 1.1.717.3.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	

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 1.1.717.4.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	

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 1.1.718.3.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	

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 1.1.718.4.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	

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 1.1.719.3.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	

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 1.1.719.4.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	

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 1.1.720.3.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.0327	0.29 (0.09, 0.97)	0.27 (0.08, 0.96)	-3.9 (-8.2, 0.34)	7	(5.6)	9	4	(1.6)	4

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 1.1.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.0178	0.12 (0.02, 0.99)	0.12 (0.01, 0.96)	-5.1 (-9.3, -.93)	8 (5.8)		12	1 (0.7)		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

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Table 1.1.721.3.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)		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. TESAESI: Treatment emergent serious adverse events of special interest

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Table 1.1.721.4.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	

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 1.1.722.3.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.1972	1.10 (0.95, 1.27)	1.37 (0.85, 2.22)	6.2 (-3.3, 15.8)	81	(64.3)	168	178	(70.6)	494

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 1.1.722.4.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Any system organ class											
Any preferred term											
Total		0.8030	0.98 (0.87, 1.12)	0.93 (0.53, 1.64)	-1.3 (-11, 8.62)	107	(78.1)	391	106	(76.8)	361

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 1.1.723.3.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Any system organ class											
Any preferred term											
Total		0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4	(3.2)	4	2	(0.8)	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. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.1.723.4.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n (%)	E	Tralokinumab Q2W + TCS n (%)	E
Analysis set N, Exposure(years) Total						137 65.4		138 65.4	
Any system organ class Any preferred term Total		0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5 (3.6)	8	1 (0.7)	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. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.3.101.3.1.1: Total, Age (>=18 and < 65), Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	118	236
Age (years)		
Mean (sd)	35.6 (12.5)	37.5 (13.0)
Gender		
Female	39 (33.1%)	118 (50.0%)
Male	79 (66.9%)	118 (50.0%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	27.2 (5.7)	27.6 (6.8)
Race		
Asian	22 (18.6%)	16 (6.8%)
Black	10 (8.5%)	20 (8.5%)
White	81 (68.6%)	190 (80.5%)
Other	5 (4.2%)	10 (4.2%)
Geographic region		
Europe	69 (58.5%)	144 (61.0%)
USA	49 (41.5%)	92 (39.0%)
Body surface area (BSA) with AD (%)		
Mean (sd)	48.9 (26.2)	47.9 (23.3)
Duration of AD (years)		
Mean (sd)	28.0 (13.6)	26.9 (14.8)
Eczema Area and Severity Index (EASI)		
Mean (sd)	30.3 (12.8)	29.0 (11.9)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	62 (52.5%)	125 (53.0%)
Severe [IGA=4]	56 (47.5%)	111 (47.0%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.9 (1.5)	7.7 (1.5)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.1 (2.2)	7.0 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	68.7 (13.4)	67.3 (13.2)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	17.3 (7.0)	17.9 (7.0)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	11.8 (7.6)	11.9 (7.4)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	58.5 (23.1)	58.3 (25.3)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.583 (0.28)	0.555 (0.28)
Patients that have tried systemic corticosteroids (%)		
No	38 (32.2%)	94 (39.8%)
Yes	80 (67.8%)	142 (60.2%)
Previous number of treatments with systemic immunosuppressants*		
0	56 (47.5%)	145 (61.4%)
1	38 (32.2%)	62 (26.3%)
2	17 (14.4%)	19 (8.1%)
3	5 (4.2%)	5 (2.1%)
4	1 (0.8%)	4 (1.7%)
5	1 (0.8%)	1 (0.4%)

Table 1.3.101.3.1.1: Total, Age (>=18 and < 65), Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

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Table 1.3.101.3.2.1: Total, Age (>=65), Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	8	16
Age (years)		
Mean (sd)	70.0 (4.2)	72.8 (5.2)
Gender		
Female	4 (50.0%)	9 (56.3%)
Male	4 (50.0%)	7 (43.8%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	24.8 (3.0)	27.8 (4.2)
Race		
Asian	2 (25.0%)	1 (6.3%)
Black	2 (25.0%)	2 (12.5%)
White	3 (37.5%)	13 (81.3%)
Other	1 (12.5%)	
Geographic region		
Europe	3 (37.5%)	3 (18.8%)
USA	5 (62.5%)	13 (81.3%)
Body surface area (BSA) with AD (%)		
Mean (sd)	47.6 (23.0)	42.6 (23.1)
Duration of AD (years)		
Mean (sd)	38.6 (29.0)	43.7 (28.1)
Eczema Area and Severity Index (EASI)		
Mean (sd)	32.0 (12.5)	26.7 (12.5)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	4 (50.0%)	11 (68.8%)
Severe [IGA=4]	4 (50.0%)	5 (31.3%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.7 (1.7)	7.3 (1.6)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.1 (2.2)	6.2 (2.2)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	70.9 (10.1)	62.1 (13.9)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	16.1 (9.3)	12.3 (5.9)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	11.8 (9.3)	8.0 (4.7)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	73.4 (19.0)	71.1 (17.4)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.670 (0.22)	0.648 (0.23)
Patients that have tried systemic corticosteroids (%)		
No	3 (37.5%)	11 (68.8%)
Yes	5 (62.5%)	5 (31.3%)
Previous number of treatments with systemic immunosuppressants*		
0	6 (75.0%)	14 (87.5%)
1	1 (12.5%)	2 (12.5%)
2	1 (12.5%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.3.101.4.1.1: Total, Age (>=18 and < 65), Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	131	132
Age (years)		
Mean (sd)	34.6 (11.9)	35.3 (12.9)
Gender		
Female	52 (39.7%)	55 (41.7%)
Male	79 (60.3%)	77 (58.3%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	25.7 (5.8)	25.1 (4.3)
Race		
Asian	1 (0.8%)	
Black	1 (0.8%)	
White	129 (98.5%)	129 (97.7%)
Other		3 (2.3%)
Geographic region		
Europe	131 (100%)	132 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	55.4 (22.9)	53.9 (21.9)
Duration of AD (years)		
Mean (sd)	25.4 (14.1)	26.9 (13.2)
Eczema Area and Severity Index (EASI)		
Mean (sd)	33.8 (13.6)	31.9 (11.5)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	67 (51.1%)	67 (50.8%)
Severe [IGA=4]	64 (48.9%)	65 (49.2%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.5 (1.3)	7.3 (1.4)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.9 (1.6)	6.4 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	70.8 (12.8)	70.3 (12.1)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	16.5 (6.3)	16.0 (6.4)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	11.9 (7.5)	10.8 (6.5)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	52.2 (22.2)	56.4 (20.2)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.589 (0.24)	0.628 (0.23)
Patients that have tried systemic corticosteroids (%)		
No	43 (32.8%)	39 (29.5%)
Yes	88 (67.2%)	93 (70.5%)
Previous number of treatments with systemic immunosuppressants*		
0	21 (16.0%)	20 (15.2%)
1	75 (57.3%)	82 (62.1%)
2	26 (19.8%)	22 (16.7%)
3	6 (4.6%)	7 (5.3%)
4	2 (1.5%)	1 (0.8%)
5	1 (0.8%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.3.101.4.2.1: Total, Age (>=65), Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	6	6
Age (years)		
Mean (sd)	69.2 (3.7)	71.5 (3.0)
Gender		
Female	2 (33.3%)	2 (33.3%)
Male	4 (66.7%)	4 (66.7%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	28.4 (3.7)	26.4 (1.9)
Race		
White	6 (100%)	6 (100%)
Geographic region		
Europe	6 (100%)	6 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	50.3 (24.5)	58.5 (20.8)
Duration of AD (years)		
Mean (sd)	24.0 (16.0)	30.7 (26.4)
Eczema Area and Severity Index (EASI)		
Mean (sd)	34.8 (10.3)	35.5 (11.5)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	3 (50.0%)	1 (16.7%)
Severe [IGA=4]	3 (50.0%)	5 (83.3%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.2 (2.2)	5.8 (2.0)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.0 (2.3)	5.0 (2.3)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	72.3 (14.8)	68.4 (12.8)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	13.7 (6.1)	12.3 (8.4)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	8.0 (6.0)	9.5 (4.6)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	58.0 (17.9)	60.3 (13.5)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.637 (0.27)	0.778 (0.15)
Patients that have tried systemic corticosteroids (%)		
No	3 (50.0%)	2 (33.3%)
Yes	3 (50.0%)	4 (66.7%)
Previous number of treatments with systemic immunosuppressants*		
0	2 (33.3%)	2 (33.3%)
1	3 (50.0%)	3 (50.0%)
2	1 (16.7%)	
3		1 (16.7%)

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

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Table 1.3.102.3.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Analysis set				
N	118		236	
Blood and lymphatic system disorders				
Anaemia			5	(2.1)
Lymphadenopathy	2	(1.7)		
Dermatopathic lymphadenopathy			1	(0.4)
Eosinophilia			1	(0.4)
Hypercoagulation			1	(0.4)
Hypereosinophilic syndrome			1	(0.4)
Iron deficiency anaemia			1	(0.4)
Leukocytosis			1	(0.4)
Lymphadenitis			1	(0.4)
Cardiac disorders				
Bundle branch block right			3	(1.3)
Atrioventricular block first degree	1	(0.8)		
Ventricular extrasystoles	1	(0.8)		
Bradycardia			1	(0.4)
Cardiac failure chronic			1	(0.4)
Congenital, familial and genetic disorders				
Atrial septal defect	2	(1.7)		
Gilbert's syndrome	2	(1.7)		
Congenital naevus	1	(0.8)		
Ichthyosis	1	(0.8)	1	(0.4)
Multiple lentigines syndrome	1	(0.8)		
Thalassaemia beta	1	(0.8)		
Arrhythmogenic right ventricular dysplasia			1	(0.4)
Deafness congenital			1	(0.4)
Sickle cell trait			1	(0.4)
Tourette's disorder			1	(0.4)
Type V hyperlipidaemia			1	(0.4)
Ear and labyrinth disorders				
Deafness bilateral	1	(0.8)	1	(0.4)
Hyperacusis	1	(0.8)		
Vertigo positional	1	(0.8)		
Vertigo			1	(0.4)
Endocrine disorders				
Hypothyroidism	4	(3.4)	11	(4.7)
Autoimmune thyroiditis			2	(0.8)
Basedow's disease			1	(0.4)
Hyperthyroidism			1	(0.4)
Thyroid mass			1	(0.4)
Eye disorders				
Conjunctivitis allergic	24	(20.3)	51	(21.6)
Atopic keratoconjunctivitis	4	(3.4)	7	(3.0)
Dry eye			3	(1.3)
Myopia			3	(1.3)
Blindness unilateral	1	(0.8)	1	(0.4)
Cataract	1	(0.8)	1	(0.4)
Glaucoma			2	(0.8)
Keratoconus	1	(0.8)	1	(0.4)
Presbyopia			2	(0.8)
Visual impairment	1	(0.8)		
Allergic keratitis			1	(0.4)
Astigmatism			1	(0.4)
Blepharitis			1	(0.4)
Blindness			1	(0.4)
Blindness day			1	(0.4)
Corneal opacity			1	(0.4)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.3.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Age (>=18 and < 65)		
Eye disorders		
Ectropion		1 (0.4)
Eczema eyelids		1 (0.4)
Eye pruritus		1 (0.4)
Eyelid oedema		1 (0.4)
Gastrointestinal disorders		
Gastrooesophageal reflux disease	4 (3.4)	14 (5.9)
Dyspepsia	3 (2.5)	4 (1.7)
Gastritis	2 (1.7)	
Haemorrhoids		3 (1.3)
Irritable bowel syndrome	1 (0.8)	3 (1.3)
Cheilitis	1 (0.8)	
Chronic gastritis	1 (0.8)	
Colitis ulcerative	1 (0.8)	1 (0.4)
Constipation	1 (0.8)	2 (0.8)
Diarrhoea	1 (0.8)	
Dysphagia	1 (0.8)	
Hiatus hernia	1 (0.8)	
Abdominal distension		1 (0.4)
Crohn's disease		1 (0.4)
Nausea		1 (0.4)
Oesophagitis		1 (0.4)
Stress ulcer		1 (0.4)
Tooth malformation		1 (0.4)
General disorders and administration site conditions		
Drug intolerance		2 (0.8)
Fatigue	1 (0.8)	
Pain		2 (0.8)
Asthenia		1 (0.4)
Drug chemical incompatibility		1 (0.4)
Hernia		1 (0.4)
Hepatobiliary disorders		
Hyperbilirubinaemia	1 (0.8)	
Immune system disorders		
Seasonal allergy	53 (44.9)	112 (47.5)
Food allergy	42 (35.6)	81 (34.3)
Drug hypersensitivity	10 (8.5)	21 (8.9)
Hypersensitivity	7 (5.9)	16 (6.8)
Allergy to animal	6 (5.1)	13 (5.5)
Multiple allergies	3 (2.5)	10 (4.2)
Dust allergy		8 (3.4)
Mite allergy	4 (3.4)	5 (2.1)
Rubber sensitivity	4 (3.4)	5 (2.1)
Allergy to chemicals	1 (0.8)	4 (1.7)
Allergy to metals	2 (1.7)	2 (0.8)
Sensitisation	2 (1.7)	
Milk allergy	1 (0.8)	3 (1.3)
Allergy to arthropod sting		2 (0.8)
Allergy to plants		2 (0.8)
Perfume sensitivity	1 (0.8)	
Mycotic allergy		1 (0.4)
Reaction to colouring		1 (0.4)
Infections and infestations		
Herpes simplex	7 (5.9)	8 (3.4)
Oral herpes	3 (2.5)	6 (2.5)
Rhinitis	2 (1.7)	4 (1.7)
Chronic sinusitis	1 (0.8)	1 (0.4)
Conjunctivitis	1 (0.8)	2 (0.8)
Eczema herpeticum	1 (0.8)	

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.3.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Infections and infestations				
Eczema herpeticum			1	(0.4)
Hordeolum	1	(0.8)		
Conjunctivitis bacterial			1	(0.4)
Folliculitis			1	(0.4)
Onychomycosis			1	(0.4)
Sinusitis			1	(0.4)
Urinary tract infection			1	(0.4)
Viral upper respiratory tract infection			1	(0.4)
Injury, poisoning and procedural complications				
Joint injury			2	(0.8)
Ligament rupture	1	(0.8)		
Muscle strain	1	(0.8)		
Foot fracture			1	(0.4)
Ligament sprain			1	(0.4)
Limb injury			1	(0.4)
Meniscus injury			1	(0.4)
Tendon injury			1	(0.4)
Tendon rupture			1	(0.4)
Tibia fracture			1	(0.4)
Ulnar nerve injury			1	(0.4)
Investigations				
Blood cholesterol increased	2	(1.7)	1	(0.4)
Alanine aminotransferase increased	1	(0.8)	1	(0.4)
Basophil count decreased	1	(0.8)		
Blood bilirubin increased	1	(0.8)		
Blood immunoglobulin E increased	1	(0.8)	2	(0.8)
Blood lactate dehydrogenase increased	1	(0.8)		
Blood pressure increased	1	(0.8)		
Blood triglycerides increased	1	(0.8)		
Cardiac murmur	1	(0.8)		
Electrocardiogram QT shortened	1	(0.8)		
Gamma-glutamyltransferase increased	1	(0.8)	1	(0.4)
Low density lipoprotein increased	1	(0.8)	1	(0.4)
Mean cell volume decreased	1	(0.8)		
Eosinophil count increased			1	(0.4)
Hepatic enzyme increased			1	(0.4)
Human papilloma virus test			1	(0.4)
Human papilloma virus test positive			1	(0.4)
Vitamin D decreased			1	(0.4)
Metabolism and nutrition disorders				
Obesity	4	(3.4)	14	(5.9)
Hypercholesterolaemia	1	(0.8)	9	(3.8)
Type 2 diabetes mellitus	3	(2.5)	8	(3.4)
Gout	3	(2.5)	3	(1.3)
Hyperlipidaemia	1	(0.8)	6	(2.5)
Lactose intolerance	1	(0.8)	6	(2.5)
Vitamin D deficiency	2	(1.7)	3	(1.3)
Gluten sensitivity			3	(1.3)
Hypertriglyceridaemia	1	(0.8)	3	(1.3)
Decreased appetite	1	(0.8)	1	(0.4)
Diabetes mellitus			2	(0.8)
Dyslipidaemia	1	(0.8)		
Cow's milk intolerance			1	(0.4)
Fructose intolerance			1	(0.4)
Glucose tolerance impaired			1	(0.4)
Hyperuricaemia			1	(0.4)
Hypoglycaemia			1	(0.4)
Hypokalaemia			1	(0.4)
Iodine deficiency			1	(0.4)
Vitamin B12 deficiency			1	(0.4)
Musculoskeletal and connective tissue disorders				

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.3.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Back pain	2	(1.7)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.3.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Musculoskeletal and connective tissue disorders				
Back pain			7	(3.0)
Osteoarthritis	2	(1.7)	7	(3.0)
Intervertebral disc protrusion			6	(2.5)
Arthralgia	2	(1.7)	4	(1.7)
Arthritis			3	(1.3)
Ankylosing spondylitis	1	(0.8)	1	(0.4)
Fibromyalgia	1	(0.8)		
Joint instability	1	(0.8)		
Muscle spasms			2	(0.8)
Pain in extremity	1	(0.8)		
Plantar fasciitis	1	(0.8)	1	(0.4)
Psoriatic arthropathy	1	(0.8)		
Scoliosis			2	(0.8)
Systemic lupus erythematosus	1	(0.8)		
Bursitis			1	(0.4)
Costochondritis			1	(0.4)
Haemarthrosis			1	(0.4)
Intervertebral disc degeneration			1	(0.4)
Intervertebral disc disorder			1	(0.4)
Limb asymmetry			1	(0.4)
Muscle tightness			1	(0.4)
Muscular weakness			1	(0.4)
Neck pain			1	(0.4)
Osteonecrosis			1	(0.4)
Osteoporosis			1	(0.4)
Rheumatoid arthritis			1	(0.4)
Temporomandibular joint syndrome			1	(0.4)
Vertebral osteophyte			1	(0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Haemangioma	1	(0.8)	1	(0.4)
Skin papilloma	1	(0.8)		
Leiomyoma			1	(0.4)
Lipoma			1	(0.4)
Uterine leiomyoma			1	(0.4)
Nervous system disorders				
Headache	3	(2.5)	10	(4.2)
Migraine	4	(3.4)	7	(3.0)
Carpal tunnel syndrome			2	(0.8)
Cervical radiculopathy	1	(0.8)		
Seizure	1	(0.8)	1	(0.4)
Tension headache	1	(0.8)		
Delayed sleep phase			1	(0.4)
Diabetic neuropathy			1	(0.4)
Dizziness			1	(0.4)
Epilepsy			1	(0.4)
Lumbar radiculopathy			1	(0.4)
Migraine with aura			1	(0.4)
Somnolence			1	(0.4)
Psychiatric disorders				
Depression	3	(2.5)	21	(8.9)
Anxiety	4	(3.4)	11	(4.7)
Insomnia	2	(1.7)	8	(3.4)
Anxiety disorder	3	(2.5)		
Autism spectrum disorder	3	(2.5)		
Attention deficit/hyperactivity disorder	2	(1.7)	3	(1.3)
Body dysmorphic disorder	1	(0.8)		
Depersonalisation/derealisation disorder	1	(0.8)		
Generalised anxiety disorder	1	(0.8)		
Sleep disorder	1	(0.8)	1	(0.4)
Stress	1	(0.8)		
Bulimia nervosa			1	(0.4)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.3.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Age (>=18 and < 65)		
Psychiatric disorders		
Oppositional defiant disorder		1 (0.4)
Post-traumatic stress disorder		1 (0.4)
Social anxiety disorder		1 (0.4)
Renal and urinary disorders		
Pollakiuria	1 (0.8)	
Renal colic	1 (0.8)	
Renal cyst	1 (0.8)	1 (0.4)
Automatic bladder		1 (0.4)
Haematuria		1 (0.4)
Renal failure		1 (0.4)
Reproductive system and breast disorders		
Dysmenorrhoea		2 (0.8)
Erectile dysfunction	1 (0.8)	1 (0.4)
Pelvic congestion	1 (0.8)	
Benign prostatic hyperplasia		1 (0.4)
Ovarian cyst		1 (0.4)
Respiratory, thoracic and mediastinal disorders		
Asthma	53 (44.9)	115 (48.7)
Rhinitis allergic	13 (11.0)	21 (8.9)
Chronic obstructive pulmonary disease	3 (2.5)	3 (1.3)
Sleep apnoea syndrome	1 (0.8)	6 (2.5)
Nasal polyps	1 (0.8)	
Rhinitis perennial	1 (0.8)	
Adenoidal hypertrophy		1 (0.4)
Dyspnoea		1 (0.4)
Lung cyst		1 (0.4)
Vocal cord dysfunction		1 (0.4)
Skin and subcutaneous tissue disorders		
Vitiligo	4 (3.4)	3 (1.3)
Acne		6 (2.5)
Alopecia areata	3 (2.5)	4 (1.7)
Androgenetic alopecia	3 (2.5)	3 (1.3)
Alopecia	2 (1.7)	3 (1.3)
Dermal cyst	2 (1.7)	1 (0.4)
Dermatitis contact	2 (1.7)	4 (1.7)
Pruritus	2 (1.7)	1 (0.4)
Alopecia universalis	1 (0.8)	
Chronic spontaneous urticaria	1 (0.8)	1 (0.4)
Dermatitis papillaris capillitii	1 (0.8)	
Dyshidrotic eczema	1 (0.8)	
Hyperkeratosis	1 (0.8)	
Neurodermatitis	1 (0.8)	1 (0.4)
Psoriasis	1 (0.8)	
Transient acantholytic dermatosis	1 (0.8)	
Urticaria	1 (0.8)	2 (0.8)
Acanthosis nigricans		1 (0.4)
Dry skin		1 (0.4)
Hidradenitis		1 (0.4)
Keratosis pilaris		1 (0.4)
Lichen sclerosus		1 (0.4)
Rosacea		1 (0.4)
Social circumstances		
Tobacco user	4 (3.4)	4 (1.7)
Postmenopause	1 (0.8)	1 (0.4)
Menopause		1 (0.4)
Surgical and medical procedures		
Appendicectomy	1 (0.8)	

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.3.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Age (>=18 and < 65)		
Surgical and medical procedures		
Caesarean section	1 (0.8)	
Heart valve replacement	1 (0.8)	1 (0.4)
Immune tolerance induction	1 (0.8)	
Osteosynthesis	1 (0.8)	
Vasectomy	1 (0.8)	
Cataract operation		1 (0.4)
Continuous positive airway pressure		1 (0.4)
Corneal transplant		1 (0.4)
Intra-uterine contraceptive device		1 (0.4)
Intra-uterine contraceptive device insertion		1 (0.4)
Keratoplasty		1 (0.4)
Knee arthroplasty		1 (0.4)
Vascular disorders		
Hypertension	15 (12.7)	33 (14.0)
Lymphoedema	1 (0.8)	
Raynaud's phenomenon	1 (0.8)	
Arteriosclerosis		1 (0.4)
Peripheral vascular disorder		1 (0.4)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.3.1: Total, Age (>=65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=65)				
Analysis set				
N	8		16	
Blood and lymphatic system disorders				
Anaemia			2	(12.5)
Cardiac disorders				
Atrial fibrillation			2	(12.5)
Bundle branch block right	1	(12.5)		
Angina pectoris			1	(6.3)
Arrhythmia			1	(6.3)
Bundle branch block left			1	(6.3)
Cardiac failure chronic			1	(6.3)
Myocardial infarction			1	(6.3)
Congenital, familial and genetic disorders				
Ichthyosis	1	(12.5)		
Type V hyperlipidaemia			1	(6.3)
Ear and labyrinth disorders				
Deafness			2	(12.5)
Deafness unilateral	1	(12.5)		
Deafness bilateral			1	(6.3)
Tinnitus			1	(6.3)
Vertigo			1	(6.3)
Eye disorders				
Conjunctivitis allergic	2	(25.0)	3	(18.8)
Blepharitis	1	(12.5)		
Cataract			2	(12.5)
Keratitis	1	(12.5)		
Gastrointestinal disorders				
Gastrooesophageal reflux disease	1	(12.5)	5	(31.3)
Pancreatic cyst	1	(12.5)		
Constipation			1	(6.3)
Diverticulum			1	(6.3)
Dyspepsia			1	(6.3)
Gastritis			1	(6.3)
Large intestine polyp			1	(6.3)
General disorders and administration site conditions				
Gait disturbance			1	(6.3)
Peripheral swelling			1	(6.3)
Hepatobiliary disorders				
Cholelithiasis			1	(6.3)
Immune system disorders				
Seasonal allergy	3	(37.5)	9	(56.3)
Food allergy	2	(25.0)	2	(12.5)
Multiple allergies			3	(18.8)
Drug hypersensitivity	1	(12.5)	1	(6.3)
Allergy to metals			1	(6.3)
Hypersensitivity			1	(6.3)
Iodine allergy			1	(6.3)
Infections and infestations				
Paronychia			1	(6.3)
Tinea versicolour			1	(6.3)
Investigations				
Blood cholesterol increased	1	(12.5)	1	(6.3)
Metabolism and nutrition disorders				
Hyperlipidaemia	1	(12.5)		

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Table 1.3.102.3.1: Total, Age (>=65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=65)				
Metabolism and nutrition disorders				
Hyperlipidaemia			3	(18.8)
Type 2 diabetes mellitus	1	(12.5)	3	(18.8)
Diabetes mellitus	1	(12.5)		
Folate deficiency	1	(12.5)		
Haemochromatosis	1	(12.5)		
Hypercholesterolaemia	1	(12.5)	2	(12.5)
Hypertriglyceridaemia			2	(12.5)
Gout			1	(6.3)
Hyperuricaemia			1	(6.3)
Overweight			1	(6.3)
Musculoskeletal and connective tissue disorders				
Osteoarthritis	1	(12.5)	4	(25.0)
Back pain			3	(18.8)
Arthritis	1	(12.5)		
Intervertebral disc degeneration	1	(12.5)		
Neck pain	1	(12.5)		
Rotator cuff syndrome	1	(12.5)		
Arthralgia			1	(6.3)
Joint swelling			1	(6.3)
Neuropathic arthropathy			1	(6.3)
Rheumatoid arthritis			1	(6.3)
Scoliosis			1	(6.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Seborrhoeic keratosis			3	(18.8)
Acoustic neuroma	1	(12.5)		
Nervous system disorders				
Headache			2	(12.5)
Diabetic neuropathy			1	(6.3)
Psychiatric disorders				
Anxiety	1	(12.5)	4	(25.0)
Insomnia	1	(12.5)	4	(25.0)
Depression			3	(18.8)
Renal and urinary disorders				
Chronic kidney disease	1	(12.5)	1	(6.3)
Renal cyst	1	(12.5)		
Reproductive system and breast disorders				
Cervical dysplasia	1	(12.5)		
Benign prostatic hyperplasia			1	(6.3)
Respiratory, thoracic and mediastinal disorders				
Asthma	5	(62.5)	4	(25.0)
Chronic obstructive pulmonary disease	1	(12.5)	4	(25.0)
Rhinitis allergic	2	(25.0)	2	(12.5)
Sleep apnoea syndrome			1	(6.3)
Skin and subcutaneous tissue disorders				
Actinic keratosis			2	(12.5)
Social circumstances				
Postmenopause	2	(25.0)	1	(6.3)
Tobacco user	1	(12.5)	1	(6.3)
Surgical and medical procedures				
Alcohol rehabilitation	1	(12.5)		
Hip arthroplasty			1	(6.3)
Vascular disorders				
Hypertension	5	(62.5)		

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Table 1.3.102.3.1: Total, Age (>=65), Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=65)				
Vascular disorders				
Hypertension			10	(62.5)
Peripheral vascular disorder			2	(12.5)
Deep vein thrombosis			1	(6.3)
Poor peripheral circulation			1	(6.3)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.4.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Analysis set				
N	131		132	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	1	(0.8)		
Thrombocytopenia	1	(0.8)		
Eosinophilia			1	(0.8)
Iron deficiency anaemia			1	(0.8)
Lymphadenopathy			1	(0.8)
Lymphopenia			1	(0.8)
Cardiac disorders				
Bundle branch block right	2	(1.5)		
Sinus bradycardia	1	(0.8)	2	(1.5)
Atrial fibrillation	1	(0.8)	1	(0.8)
Atrial flutter	1	(0.8)		
Atrioventricular block	1	(0.8)		
Atrioventricular block first degree			1	(0.8)
Bradycardia			1	(0.8)
Bundle branch block left			1	(0.8)
Congestive cardiomyopathy			1	(0.8)
Mitral valve incompetence			1	(0.8)
Tachycardia			1	(0.8)
Congenital, familial and genetic disorders				
Benign familial haematuria	1	(0.8)		
Congenital anomaly	1	(0.8)		
Congenital cystic kidney disease	1	(0.8)		
Cytogenetic abnormality	1	(0.8)		
Gilbert's syndrome	1	(0.8)		
Sickle cell anaemia	1	(0.8)		
Von Willebrand's disease			1	(0.8)
Ear and labyrinth disorders				
Deafness neurosensory	1	(0.8)		
Tinnitus	1	(0.8)		
Endocrine disorders				
Hypothyroidism	2	(1.5)	9	(6.8)
Autoimmune thyroiditis	3	(2.3)		
Thyroid mass	1	(0.8)		
Goitre			1	(0.8)
Hyperprolactinaemia			1	(0.8)
Thyroiditis			1	(0.8)
Eye disorders				
Conjunctivitis allergic	40	(30.5)	40	(30.3)
Atopic keratoconjunctivitis	9	(6.9)	1	(0.8)
Keratoconus	3	(2.3)		
Dry eye	2	(1.5)		
Myopia			2	(1.5)
Astigmatism	1	(0.8)		
Glaucoma	1	(0.8)	1	(0.8)
Blepharitis			1	(0.8)
Cataract			1	(0.8)
Keratitis			1	(0.8)
Photophobia			1	(0.8)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	3	(2.3)	3	(2.3)
Irritable bowel syndrome	2	(1.5)	1	(0.8)
Dyspepsia			2	(1.5)
Oesophagitis			2	(1.5)
Barrett's oesophagus	1	(0.8)		

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Table 1.3.102.4.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Age (>=18 and < 65)		
Gastrointestinal disorders		
Chronic gastritis	1 (0.8)	
Coeliac disease	1 (0.8)	1 (0.8)
Crohn's disease	1 (0.8)	
Gastritis	1 (0.8)	
Haemorrhoids	1 (0.8)	1 (0.8)
Hiatus hernia	1 (0.8)	1 (0.8)
Colitis ulcerative		1 (0.8)
Gastric ulcer		1 (0.8)
General disorders and administration site conditions		
Xerosis	1 (0.8)	4 (3.0)
Dysplasia	1 (0.8)	
Hernia	1 (0.8)	
Oedema peripheral	1 (0.8)	
Hepatobiliary disorders		
Hepatic steatosis		1 (0.8)
Immune system disorders		
Seasonal allergy	67 (51.1)	74 (56.1)
Food allergy	48 (36.6)	50 (37.9)
Allergy to animal	17 (13.0)	10 (7.6)
Mite allergy	16 (12.2)	14 (10.6)
Drug hypersensitivity	7 (5.3)	11 (8.3)
Multiple allergies	9 (6.9)	11 (8.3)
Hypersensitivity	4 (3.1)	3 (2.3)
Allergy to metals	1 (0.8)	4 (3.0)
Allergy to plants	3 (2.3)	4 (3.0)
Rubber sensitivity	1 (0.8)	4 (3.0)
Milk allergy	1 (0.8)	3 (2.3)
Allergy to chemicals	1 (0.8)	2 (1.5)
Dust allergy	1 (0.8)	2 (1.5)
Flour sensitivity	1 (0.8)	
Mycotic allergy	1 (0.8)	1 (0.8)
Iodine allergy		1 (0.8)
Oral allergy syndrome		1 (0.8)
Perfume sensitivity		1 (0.8)
Infections and infestations		
Herpes simplex	10 (7.6)	13 (9.8)
Sinusitis	2 (1.5)	1 (0.8)
Oral herpes	1 (0.8)	2 (1.5)
Rhinitis		2 (1.5)
Conjunctivitis	1 (0.8)	
Onychomycosis	1 (0.8)	
Ear infection		1 (0.8)
Epididymitis		1 (0.8)
Papilloma viral infection		1 (0.8)
Skin candida		1 (0.8)
Injury, poisoning and procedural complications		
Scar		2 (1.5)
Deafness traumatic	1 (0.8)	
Joint injury		1 (0.8)
Ligament sprain		1 (0.8)
Meniscus injury		1 (0.8)
Investigations		
Aspartate aminotransferase increased	1 (0.8)	
Blood immunoglobulin E increased	1 (0.8)	1 (0.8)
Gamma-glutamyltransferase increased	1 (0.8)	
Lymph node palpable	1 (0.8)	

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Table 1.3.102.4.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Investigations				
Mean cell volume increased	1	(0.8)		
Neutrophil count increased	1	(0.8)		
Vitamin B12 decreased	1	(0.8)		
White blood cell count increased	1	(0.8)		
Blood uric acid increased			1	(0.8)
Metabolism and nutrition disorders				
Hypercholesterolaemia	2	(1.5)	4	(3.0)
Dyslipidaemia	3	(2.3)	1	(0.8)
Gluten sensitivity	3	(2.3)		
Lactose intolerance	3	(2.3)		
Vitamin D deficiency	2	(1.5)	2	(1.5)
Diabetes mellitus			2	(1.5)
Hyperuricaemia			2	(1.5)
Obesity	1	(0.8)	2	(1.5)
Glucose tolerance impaired	1	(0.8)		
Gout	1	(0.8)		
Hyperlipidaemia	1	(0.8)	1	(0.8)
Iron deficiency	1	(0.8)	1	(0.8)
Mineral deficiency	1	(0.8)		
Histamine intolerance			1	(0.8)
Hyperinsulinism			1	(0.8)
Hypertriglyceridaemia			1	(0.8)
Overweight			1	(0.8)
Purine metabolism disorder			1	(0.8)
Musculoskeletal and connective tissue disorders				
Back pain	1	(0.8)	5	(3.8)
Intervertebral disc protrusion	2	(1.5)	3	(2.3)
Arthralgia	2	(1.5)		
Myalgia	2	(1.5)		
Osteopenia	2	(1.5)		
Osteoarthritis	1	(0.8)	2	(1.5)
Growth retardation	1	(0.8)		
Intervertebral disc disorder	1	(0.8)		
Joint range of motion decreased	1	(0.8)		
Osteochondrosis	1	(0.8)		
Plica syndrome	1	(0.8)		
Spinal osteoarthritis	1	(0.8)		
Temporomandibular joint syndrome	1	(0.8)		
Ankylosing spondylitis			1	(0.8)
Fibromyalgia			1	(0.8)
Foot deformity			1	(0.8)
Lumbar spinal stenosis			1	(0.8)
Muscle spasms			1	(0.8)
Osteoporosis			1	(0.8)
Spinal pain			1	(0.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Melanocytic naevus			4	(3.0)
Haemangioma	1	(0.8)		
Blepharal papilloma			1	(0.8)
Fibroma			1	(0.8)
Haemangioma of liver			1	(0.8)
Skin papilloma			1	(0.8)
Nervous system disorders				
Headache	5	(3.8)	7	(5.3)
Migraine	5	(3.8)	6	(4.5)
Dysaesthesia	1	(0.8)		
Epilepsy	1	(0.8)		
Hydrocephalus	1	(0.8)		
Migraine with aura	1	(0.8)		

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Table 1.3.102.4.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Age (>=18 and < 65)		
Nervous system disorders		
Multiple sclerosis	1 (0.8)	
Narcolepsy	1 (0.8)	
Paralysis	1 (0.8)	
Restless legs syndrome	1 (0.8)	
Psychiatric disorders		
Anxiety	1 (0.8)	5 (3.8)
Depression	2 (1.5)	3 (2.3)
Insomnia	2 (1.5)	1 (0.8)
Depressed mood	1 (0.8)	2 (1.5)
Eating disorder	1 (0.8)	
Fear of injection	1 (0.8)	
Nervousness	1 (0.8)	
Affective disorder		1 (0.8)
Attention deficit/hyperactivity disorder		1 (0.8)
Sleep disorder		1 (0.8)
Stress		1 (0.8)
Renal and urinary disorders		
Proteinuria	4 (3.1)	
Haematuria	2 (1.5)	
Nephrolithiasis		2 (1.5)
Renal cyst	1 (0.8)	
Renal disorder	1 (0.8)	
Renal vein compression	1 (0.8)	
Chronic kidney disease		1 (0.8)
IgA nephropathy		1 (0.8)
Renal failure		1 (0.8)
Reproductive system and breast disorders		
Benign prostatic hyperplasia	1 (0.8)	1 (0.8)
Dysmenorrhoea	1 (0.8)	1 (0.8)
Erectile dysfunction	1 (0.8)	
Menstrual disorder	1 (0.8)	
Polycystic ovaries	1 (0.8)	
Premenstrual syndrome	1 (0.8)	
Gynaecomastia		1 (0.8)
Ovarian cyst		1 (0.8)
Testicular cyst		1 (0.8)
Respiratory, thoracic and mediastinal disorders		
Asthma	73 (55.7)	61 (46.2)
Rhinitis allergic	20 (15.3)	9 (6.8)
Nasal septum deviation	2 (1.5)	2 (1.5)
Bronchial hyperreactivity	1 (0.8)	
Nasal polyps	1 (0.8)	
Sinus disorder	1 (0.8)	
Bronchitis chronic		1 (0.8)
Dysphonia		1 (0.8)
Nasal turbinate hypertrophy		1 (0.8)
Skin and subcutaneous tissue disorders		
Alopecia areata	3 (2.3)	1 (0.8)
Alopecia	2 (1.5)	
Acne		2 (1.5)
Dermatitis contact	1 (0.8)	1 (0.8)
Psoriasis	1 (0.8)	
Skin sensitisation	1 (0.8)	
Urticaria	1 (0.8)	1 (0.8)
Vitiligo	1 (0.8)	1 (0.8)
Androgenetic alopecia		1 (0.8)
Photosensitivity reaction		1 (0.8)
Rosacea		1 (0.8)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.4.1: Total, Age (>=18 and < 65), Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Social circumstances				
Menopause			2	(1.5)
Postmenopause	1	(0.8)		
Surgical and medical procedures				
Female sterilisation	1	(0.8)		
Gastric bypass	1	(0.8)		
Lip lesion excision	1	(0.8)		
Maxillofacial operation	1	(0.8)		
Nasal septal operation	1	(0.8)		
Sterilisation	1	(0.8)		
Thyroid nodule removal	1	(0.8)		
Thyroidectomy	1	(0.8)		
Cardiac pacemaker insertion			1	(0.8)
Cardiac resynchronisation therapy			1	(0.8)
Contraception			1	(0.8)
Intra-uterine contraceptive device			1	(0.8)
Knee operation			1	(0.8)
Vascular disorders				
Hypertension	19	(14.5)	20	(15.2)
Varicose vein	1	(0.8)	1	(0.8)
Peripheral venous disease			1	(0.8)
Spider vein			1	(0.8)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.4.1: Total, Age (>=65), Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=65)				
Analysis set				
N	6		6	
Cardiac disorders				
Atrial fibrillation			1	(16.7)
Bundle branch block right	1	(16.7)		
Cardiomyopathy	1	(16.7)		
Myocardial infarction	1	(16.7)		
Myocardial ischaemia	1	(16.7)		
Ear and labyrinth disorders				
Deafness	1	(16.7)		
Eye disorders				
Cataract			2	(33.3)
Blepharitis			1	(16.7)
Conjunctivitis allergic	1	(16.7)		
Dry eye	1	(16.7)		
Retinal degeneration			1	(16.7)
Gastrointestinal disorders				
Barrett's oesophagus			1	(16.7)
Chronic gastritis	1	(16.7)	1	(16.7)
Gastrooesophageal reflux disease			1	(16.7)
Hiatus hernia	1	(16.7)		
Immune system disorders				
Seasonal allergy	3	(50.0)	2	(33.3)
Drug hypersensitivity	2	(33.3)	1	(16.7)
Food allergy	2	(33.3)		
Allergy to chemicals			1	(16.7)
Allergy to metals			1	(16.7)
Infections and infestations				
Herpes simplex	1	(16.7)		
Investigations				
Gamma-glutamyltransferase increased			1	(16.7)
Metabolism and nutrition disorders				
Diabetes mellitus			2	(33.3)
Gout	2	(33.3)		
Hypercholesterolaemia	1	(16.7)	1	(16.7)
Hyperlipidaemia	1	(16.7)		
Hyperuricaemia	1	(16.7)		
Obesity	1	(16.7)		
Type 2 diabetes mellitus	1	(16.7)		
Musculoskeletal and connective tissue disorders				
Arthralgia	1	(16.7)		
Osteoarthritis	1	(16.7)	1	(16.7)
Osteoporosis	1	(16.7)	1	(16.7)
Nervous system disorders				
Hypertonia			2	(33.3)
Restless legs syndrome	1	(16.7)		
Psychiatric disorders				
Depression	2	(33.3)		
Sleep disorder	1	(16.7)		
Renal and urinary disorders				
Incontinence	1	(16.7)		
Renal failure	1	(16.7)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.102.4.1: Total, Age (>=65), Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=65)				
Reproductive system and breast disorders				
Benign prostatic hyperplasia	1	(16.7)		
Respiratory, thoracic and mediastinal disorders				
Chronic obstructive pulmonary disease			2	(33.3)
Asthma	1	(16.7)	1	(16.7)
Bronchiectasis			1	(16.7)
Sleep apnoea syndrome			1	(16.7)
Skin and subcutaneous tissue disorders				
Photosensitivity reaction	1	(16.7)		
Vascular disorders				
Hypertension	6	(100)	3	(50.0)
Peripheral venous disease	2	(33.3)	2	(33.3)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.103.3.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Analysis set				
N	118		236	
Blood and lymphatic system disorders				
Dermatopathic lymphadenopathy	1	(0.8)		
Iron deficiency anaemia	1	(0.8)		
Cardiac disorders				
Myocardial infarction			3	(1.3)
Arrhythmia			1	(0.4)
Pericarditis			1	(0.4)
Wolff-Parkinson-White syndrome			1	(0.4)
Congenital, familial and genetic disorders				
Cryptorchism	1	(0.8)		
Phimosis	1	(0.8)		
Ventricular septal defect	1	(0.8)		
Ear and labyrinth disorders				
Ear disorder	1	(0.8)		
Eye disorders				
Conjunctivitis allergic	3	(2.5)	1	(0.4)
Atopic keratoconjunctivitis	2	(1.7)		
Blepharitis	1	(0.8)	1	(0.4)
Cataract	1	(0.8)	2	(0.8)
Keratoconus	1	(0.8)		
Myopia	1	(0.8)	1	(0.4)
Dry eye			1	(0.4)
Retinal detachment			1	(0.4)
Strabismus			1	(0.4)
Gastrointestinal disorders				
Chronic gastritis	1	(0.8)		
Haemorrhoids	1	(0.8)	1	(0.4)
Inguinal hernia	1	(0.8)	2	(0.8)
Abdominal hernia			1	(0.4)
Colitis			1	(0.4)
Gastrooesophageal reflux disease			1	(0.4)
Gingival recession			1	(0.4)
Lumbar hernia			1	(0.4)
Oesophagitis			1	(0.4)
Peptic ulcer			1	(0.4)
General disorders and administration site conditions				
Chest pain			1	(0.4)
Cyst			1	(0.4)
Fatigue			1	(0.4)
Inflammation			1	(0.4)
Hepatobiliary disorders				
Cholecystitis			1	(0.4)
Hepatic steatosis			1	(0.4)
Hepatitis			1	(0.4)
Immune system disorders				
Food allergy	3	(2.5)	3	(1.3)
Seasonal allergy			4	(1.7)
Allergy to animal			2	(0.8)
Drug hypersensitivity			1	(0.4)
Infections and infestations				
Eczema herpeticum	6	(5.1)	4	(1.7)
Impetigo	4	(3.4)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.103.3.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Infections and infestations				
Impetigo			6	(2.5)
Erysipelas	2	(1.7)		
Herpes simplex	2	(1.7)	3	(1.3)
Herpes zoster	2	(1.7)	3	(1.3)
Oral herpes	2	(1.7)	1	(0.4)
Staphylococcal skin infection	2	(1.7)		
Conjunctivitis			3	(1.3)
Sinusitis			3	(1.3)
Tonsillitis			3	(1.3)
Appendicitis			2	(0.8)
Bronchitis	1	(0.8)	1	(0.4)
Cellulitis	1	(0.8)	2	(0.8)
Fungal infection	1	(0.8)		
Furuncle			2	(0.8)
Gastrointestinal candidiasis	1	(0.8)		
Herpes virus infection	1	(0.8)		
Measles	1	(0.8)		
Molluscum contagiosum	1	(0.8)		
Osteomyelitis	1	(0.8)		
Peritonsillitis	1	(0.8)		
Poliomyelitis	1	(0.8)		
Staphylococcal infection	1	(0.8)	2	(0.8)
Varicella	1	(0.8)		
Abscess limb			1	(0.4)
Acarodermatitis			1	(0.4)
Acne pustular			1	(0.4)
Acute sinusitis			1	(0.4)
Adenoiditis			1	(0.4)
Ascariasis			1	(0.4)
Body tinea			1	(0.4)
Chronic tonsillitis			1	(0.4)
Conjunctivitis bacterial			1	(0.4)
Croup infectious			1	(0.4)
Dermatitis infected			1	(0.4)
External ear cellulitis			1	(0.4)
Keratitis viral			1	(0.4)
Lyme disease			1	(0.4)
Neuroborreliosis			1	(0.4)
Oesophageal candidiasis			1	(0.4)
Otitis media			1	(0.4)
Papilloma viral infection			1	(0.4)
Pilonidal cyst			1	(0.4)
Pneumonia			1	(0.4)
Tinea cruris			1	(0.4)
Tinea pedis			1	(0.4)
Urinary tract infection bacterial			1	(0.4)
Viral upper respiratory tract infection			1	(0.4)
Vulvovaginal mycotic infection			1	(0.4)
Wound infection staphylococcal			1	(0.4)
Injury, poisoning and procedural complications				
Foot fracture	2	(1.7)	1	(0.4)
Cartilage injury	1	(0.8)		
Clavicle fracture	1	(0.8)	1	(0.4)
Hand fracture	1	(0.8)		
Ligament rupture	1	(0.8)	2	(0.8)
Radius fracture	1	(0.8)		
Upper limb fracture			2	(0.8)
Wrist fracture	1	(0.8)		
Arthropod bite			1	(0.4)
Concussion			1	(0.4)
Femoral neck fracture			1	(0.4)
Injury			1	(0.4)
Jaw fracture			1	(0.4)

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Table 1.3.103.3.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Injury, poisoning and procedural complications				
Meniscus injury			1	(0.4)
Investigations				
Arthroscopy	1	(0.8)	1	(0.4)
Blood pressure increased	1	(0.8)		
Colonoscopy	1	(0.8)	2	(0.8)
Endoscopy upper gastrointestinal tract	1	(0.8)		
Blood creatinine increased			1	(0.4)
Endoscopy			1	(0.4)
Hysteroscopy			1	(0.4)
Laparoscopy			1	(0.4)
Smear cervix			1	(0.4)
Metabolism and nutrition disorders				
Hypercholesterolaemia	1	(0.8)	1	(0.4)
Type 2 diabetes mellitus			1	(0.4)
Musculoskeletal and connective tissue disorders				
Arthralgia	1	(0.8)	1	(0.4)
Intervertebral disc protrusion	1	(0.8)	1	(0.4)
Juvenile idiopathic arthritis	1	(0.8)		
Limb mass	1	(0.8)		
Back pain			1	(0.4)
Exostosis			1	(0.4)
Osteochondrosis			1	(0.4)
Pain in extremity			1	(0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Haemangioma	2	(1.7)		
Acanthoma	1	(0.8)		
Basal cell carcinoma	1	(0.8)		
Cervix carcinoma	1	(0.8)		
Anogenital warts			1	(0.4)
Dysplastic naevus			1	(0.4)
Lip squamous cell carcinoma			1	(0.4)
Osteochondroma			1	(0.4)
Skin papilloma			1	(0.4)
Nervous system disorders				
Cerebrovascular accident	1	(0.8)	1	(0.4)
Hydrocephalus	1	(0.8)		
Migraine			2	(0.8)
Alcoholic seizure			1	(0.4)
Facial paresis			1	(0.4)
Headache			1	(0.4)
Sciatica			1	(0.4)
Pregnancy, puerperium and perinatal conditions				
Abortion			1	(0.4)
Abortion spontaneous			1	(0.4)
Ectopic pregnancy			1	(0.4)
Gestational hypertension			1	(0.4)
Psychiatric disorders				
Depression	3	(2.5)	5	(2.1)
Alcohol problem			1	(0.4)
Anxiety			1	(0.4)
Depressed mood			1	(0.4)
Drug use disorder			1	(0.4)
Renal and urinary disorders				
Glomerulonephritis			1	(0.4)
Reproductive system and breast disorders				
Testicular retraction	1	(0.8)		

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Table 1.3.103.3.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Age (>=18 and < 65)		
Reproductive system and breast disorders		
Cervical dysplasia		1 (0.4)
Dysmenorrhoea		1 (0.4)
Ovarian cyst		1 (0.4)
Ovarian cyst ruptured		1 (0.4)
Uterine polyp		1 (0.4)
Respiratory, thoracic and mediastinal disorders		
Asthma	6 (5.1)	13 (5.5)
Nasal septum deviation	2 (1.7)	
Nasal inflammation	1 (0.8)	
Dyspnoea		1 (0.4)
Sleep apnoea syndrome		1 (0.4)
Skin and subcutaneous tissue disorders		
Acne	1 (0.8)	1 (0.4)
Dyshidrotic eczema		2 (0.8)
Neurodermatitis	1 (0.8)	
Urticaria	1 (0.8)	2 (0.8)
Dermatitis contact		1 (0.4)
Eczema		1 (0.4)
Hypersensitivity vasculitis		1 (0.4)
Psoriasis		1 (0.4)
Rosacea		1 (0.4)
Social circumstances		
Infant		1 (0.4)
Postmenopause		1 (0.4)
Surgical and medical procedures		
Tonsillectomy	4 (3.4)	12 (5.1)
Appendicectomy	4 (3.4)	11 (4.7)
Caesarean section	1 (0.8)	9 (3.8)
Hysterectomy	3 (2.5)	5 (2.1)
Knee operation	3 (2.5)	3 (1.3)
Wisdom teeth removal	3 (2.5)	2 (0.8)
Cholecystectomy		5 (2.1)
Corneal transplant	2 (1.7)	
Eye operation	2 (1.7)	
Female sterilisation	2 (1.7)	4 (1.7)
Haemorrhoid operation	2 (1.7)	
Nasal septal operation	2 (1.7)	1 (0.4)
Skin neoplasm excision	2 (1.7)	
Cardiac ablation		3 (1.3)
Foot operation		3 (1.3)
Inguinal hernia repair		3 (1.3)
Salpingectomy		3 (1.3)
Strabismus correction		3 (1.3)
Adenoidectomy		2 (0.8)
Arthrodesis	1 (0.8)	
Carpal tunnel decompression		2 (0.8)
Cataract operation		2 (0.8)
Circumcision	1 (0.8)	1 (0.4)
Cyst removal	1 (0.8)	
Endodontic procedure	1 (0.8)	1 (0.4)
Endometrial ablation	1 (0.8)	2 (0.8)
Gastric bypass	1 (0.8)	1 (0.4)
Heart valve replacement	1 (0.8)	
Hernia repair		2 (0.8)
Intraocular lens implant		2 (0.8)
Keratoplasty	1 (0.8)	
Laser therapy	1 (0.8)	
Ligament operation	1 (0.8)	2 (0.8)
Mammoplasty	1 (0.8)	

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Table 1.3.103.3.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Surgical and medical procedures				
Metabolic surgery	1	(0.8)		
Nasal operation			2	(0.8)
Nasal polypectomy			2	(0.8)
Plastic surgery	1	(0.8)		
Renal stone removal			2	(0.8)
Salpingo-oophorectomy	1	(0.8)		
Spinal decompression	1	(0.8)		
Spinal operation			2	(0.8)
Steroid therapy	1	(0.8)		
Toe operation			2	(0.8)
Transfusion	1	(0.8)		
Vasectomy	1	(0.8)	2	(0.8)
Abdominal hernia repair			1	(0.4)
Angioplasty			1	(0.4)
Ankle arthroplasty			1	(0.4)
Ankle operation			1	(0.4)
Aortic bypass			1	(0.4)
Balneotherapy			1	(0.4)
Bone lesion excision			1	(0.4)
Bone operation			1	(0.4)
Brain lobectomy			1	(0.4)
Cardiac resynchronisation therapy			1	(0.4)
Carotid artery bypass			1	(0.4)
Explorative laparotomy			1	(0.4)
Eye laser surgery			1	(0.4)
Eyelid operation			1	(0.4)
Fracture treatment			1	(0.4)
Gingival graft			1	(0.4)
Hepatitis B immunisation			1	(0.4)
Hepatitis immunisation			1	(0.4)
Hernia hiatus repair			1	(0.4)
Immunisation			1	(0.4)
Implantable defibrillator insertion			1	(0.4)
In vitro fertilisation			1	(0.4)
Incisional drainage			1	(0.4)
Intervertebral disc operation			1	(0.4)
Keratomileusis			1	(0.4)
Limb operation			1	(0.4)
Lithotripsy			1	(0.4)
Meniscus operation			1	(0.4)
Myomectomy			1	(0.4)
Myopia correction			1	(0.4)
Oesophagogastric fundoplasty			1	(0.4)
Oophorectomy			1	(0.4)
Oral surgery			1	(0.4)
Osteosynthesis			1	(0.4)
Otoplasty			1	(0.4)
Ovarian cystectomy			1	(0.4)
Papilloma excision			1	(0.4)
Phototherapy			1	(0.4)
Rhinoplasty			1	(0.4)
Sinus operation			1	(0.4)
Skin graft			1	(0.4)
Spinal fusion surgery			1	(0.4)
Spinal laminectomy			1	(0.4)
Splenectomy			1	(0.4)
Stent placement			1	(0.4)
Tenoplasty			1	(0.4)
Uterine dilation and curettage			1	(0.4)
Uvulectomy			1	(0.4)
Vascular disorders				
Kawasaki's disease	1	(0.8)		

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Table 1.3.103.3.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Vascular disorders				
Hypertension			1	(0.4)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.103.3.1: Total, Age (>=65), Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=65)				
Analysis set				
N	8		16	
Eye disorders				
Cataract	1	(12.5)	2	(12.5)
Retinal detachment	1	(12.5)		
Gastrointestinal disorders				
Haemorrhoids	1	(12.5)	1	(6.3)
Inguinal hernia	1	(12.5)		
Abdominal adhesions			1	(6.3)
Rectal prolapse			1	(6.3)
Umbilical hernia			1	(6.3)
Hepatobiliary disorders				
Cholecystitis	1	(12.5)	1	(6.3)
Infections and infestations				
Appendicitis	1	(12.5)	2	(12.5)
Chronic sinusitis	1	(12.5)		
Clostridium difficile colitis			1	(6.3)
Impetigo			1	(6.3)
Kidney infection			1	(6.3)
Oral herpes			1	(6.3)
Injury, poisoning and procedural complications				
Fall	1	(12.5)		
Wrist fracture	1	(12.5)		
Investigations				
Arthroscopy	1	(12.5)		
Catheterisation cardiac			1	(6.3)
Metabolism and nutrition disorders				
Protein deficiency	1	(12.5)		
Musculoskeletal and connective tissue disorders				
Rotator cuff syndrome	1	(12.5)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Meningioma	1	(12.5)		
Basal cell carcinoma			1	(6.3)
Colon cancer			1	(6.3)
Nervous system disorders				
Cerebrovascular accident	1	(12.5)		
Trigeminal neuralgia	1	(12.5)		
Renal and urinary disorders				
Nephrolithiasis			2	(12.5)
Reproductive system and breast disorders				
Menorrhagia	1	(12.5)		
Respiratory, thoracic and mediastinal disorders				
Nasal polyps	1	(12.5)		
Asthma			1	(6.3)
Skin and subcutaneous tissue disorders				
Urticaria	1	(12.5)		
Papulopustular rosacea			1	(6.3)
Surgical and medical procedures				
Cholecystectomy	1	(12.5)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.103.3.1: Total, Age (>=65), Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Age (>=65)		
Surgical and medical procedures		
Cholecystectomy		3 (18.8)
Appendicectomy	1 (12.5)	2 (12.5)
Cataract operation	1 (12.5)	2 (12.5)
Craniotomy	1 (12.5)	
Eye operation	1 (12.5)	
Female sterilisation	1 (12.5)	
Haemorrhoid operation	1 (12.5)	1 (6.3)
Hysterectomy	1 (12.5)	2 (12.5)
Muscle operation	1 (12.5)	
Nasal operation	1 (12.5)	
Open reduction of fracture	1 (12.5)	
Spinal fusion surgery	1 (12.5)	
Turbinoplasty	1 (12.5)	
Uterine dilation and curettage	1 (12.5)	
Adenotonsillectomy		1 (6.3)
Aortic bypass		1 (6.3)
Caesarean section		1 (6.3)
Colectomy		1 (6.3)
Explorative laparotomy		1 (6.3)
Limb operation		1 (6.3)
Peritoneal adhesions division		1 (6.3)
Rectal prolapse repair		1 (6.3)
Renal stone removal		1 (6.3)
Skin neoplasm excision		1 (6.3)
Umbilical hernia repair		1 (6.3)
Vasectomy		1 (6.3)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.103.4.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Analysis set				
N	131		132	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	2	(1.5)		
Iron deficiency anaemia	1	(0.8)		
Neutropenia	1	(0.8)		
Cardiac disorders				
Cardiac failure	1	(0.8)		
Myocardial ischaemia			1	(0.8)
Pericarditis			1	(0.8)
Congenital, familial and genetic disorders				
Phimosis			2	(1.5)
Endocrine disorders				
Basedow's disease	1	(0.8)		
Goitre	1	(0.8)		
Thyroid mass			1	(0.8)
Eye disorders				
Conjunctivitis allergic	4	(3.1)	3	(2.3)
Cataract			2	(1.5)
Corneal oedema	1	(0.8)		
Keratitis	1	(0.8)	1	(0.8)
Lacrimation increased	1	(0.8)		
Atopic keratoconjunctivitis			1	(0.8)
Keratoconus			1	(0.8)
Retinal detachment			1	(0.8)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	1	(0.8)		
Pancreatitis acute	1	(0.8)		
Haemorrhoids			1	(0.8)
Hiatus hernia			1	(0.8)
Inguinal hernia			1	(0.8)
Intestinal obstruction			1	(0.8)
Proctitis			1	(0.8)
General disorders and administration site conditions				
Dysplasia	1	(0.8)		
Hernia			1	(0.8)
Hypothermia			1	(0.8)
Immune system disorders				
Seasonal allergy			2	(1.5)
Corneal graft rejection	1	(0.8)		
Hypersensitivity	1	(0.8)		
Oral allergy syndrome	1	(0.8)		
Mite allergy			1	(0.8)
Infections and infestations				
Impetigo	10	(7.6)	5	(3.8)
Eczema herpeticum	6	(4.6)	2	(1.5)
Herpes zoster	6	(4.6)	5	(3.8)
Herpes simplex	3	(2.3)	6	(4.5)
Infectious mononucleosis	2	(1.5)		
Meningitis	2	(1.5)		
Ophthalmic herpes simplex	2	(1.5)		
Oral herpes	2	(1.5)		
Varicella	2	(1.5)	2	(1.5)
Meningitis viral			2	(1.5)
Appendicitis	1	(0.8)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.103.4.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Age (>=18 and < 65)		
Infections and infestations		
Conjunctivitis	1 (0.8)	1 (0.8)
Dermatitis infected	1 (0.8)	
Enterobiasis	1 (0.8)	
Epiglottitis	1 (0.8)	
Furuncle	1 (0.8)	
Helicobacter gastritis	1 (0.8)	
Mumps	1 (0.8)	
Otitis externa	1 (0.8)	
Pilonidal cyst	1 (0.8)	
Pneumonia	1 (0.8)	
Postoperative wound infection	1 (0.8)	
Pyelonephritis	1 (0.8)	
Rhinitis	1 (0.8)	
Skin bacterial infection	1 (0.8)	
Staphylococcal infection	1 (0.8)	
Tinea cruris	1 (0.8)	
Tuberculosis	1 (0.8)	
Upper respiratory tract infection	1 (0.8)	
Urinary tract infection	1 (0.8)	
Bacterial infection		1 (0.8)
Cellulitis		1 (0.8)
Erysipelas		1 (0.8)
Groin abscess		1 (0.8)
Herpes ophthalmic		1 (0.8)
Infection parasitic		1 (0.8)
Myringitis		1 (0.8)
Otitis media		1 (0.8)
Post procedural infection		1 (0.8)
Staphylococcal skin infection		1 (0.8)
Vaginal infection		1 (0.8)
Vulvovaginal candidiasis		1 (0.8)
Injury, poisoning and procedural complications		
Joint injury	2 (1.5)	
Upper limb fracture	2 (1.5)	2 (1.5)
Chillblains	1 (0.8)	
Clavicle fracture	1 (0.8)	
Facial bones fracture	1 (0.8)	1 (0.8)
Femur fracture	1 (0.8)	
Hand fracture	1 (0.8)	
Humerus fracture	1 (0.8)	
Joint dislocation	1 (0.8)	
Ligament injury	1 (0.8)	
Ligament rupture	1 (0.8)	
Meniscus injury	1 (0.8)	
Wound secretion	1 (0.8)	
Ankle fracture		1 (0.8)
Comminuted fracture		1 (0.8)
Foot fracture		1 (0.8)
Ligament sprain		1 (0.8)
Limb fracture		1 (0.8)
Post-traumatic neck syndrome		1 (0.8)
Spinal fracture		1 (0.8)
Tibia fracture		1 (0.8)
Wrist fracture		1 (0.8)
Investigations		
Arthroscopy	1 (0.8)	
Biopsy breast	1 (0.8)	
Biopsy lymph gland	1 (0.8)	
Skin test	1 (0.8)	
Metabolism and nutrition disorders		
Hypoproteinaemia	1 (0.8)	

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.3.103.4.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Metabolism and nutrition disorders				
Starvation	1	(0.8)		
Lactose intolerance			1	(0.8)
Musculoskeletal and connective tissue disorders				
Bursitis	1	(0.8)		
Intervertebral disc protrusion	1	(0.8)		
Osteoarthritis	1	(0.8)		
Osteochondrosis	1	(0.8)		
Foot deformity			1	(0.8)
Joint contracture			1	(0.8)
Lumbar spinal stenosis			1	(0.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Anogenital warts	2	(1.5)		
Acanthoma	1	(0.8)		
Benign pancreatic neoplasm	1	(0.8)		
Bowen's disease	1	(0.8)		
Breast cancer	1	(0.8)		
Melanocytic naevus	1	(0.8)		
Papilloma	1	(0.8)		
Skin papilloma	1	(0.8)		
Hodgkin's disease			1	(0.8)
Renal cancer			1	(0.8)
Sweat gland tumour			1	(0.8)
Testis cancer			1	(0.8)
Nervous system disorders				
Epilepsy	2	(1.5)		
Migraine	1	(0.8)	1	(0.8)
Restless legs syndrome	1	(0.8)		
Cerebral ischaemia			1	(0.8)
Paraesthesia			1	(0.8)
Seizure			1	(0.8)
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous	1	(0.8)		
HELLP syndrome	1	(0.8)		
Psychiatric disorders				
Depression	2	(1.5)	5	(3.8)
Alcoholism	1	(0.8)		
Insomnia	1	(0.8)		
Mood altered	1	(0.8)		
Stress	1	(0.8)		
Adjustment disorder with depressed mood			1	(0.8)
Anxiety			1	(0.8)
Panic attack			1	(0.8)
Renal and urinary disorders				
Nephrolithiasis	2	(1.5)		
Acute kidney injury	1	(0.8)		
Hydronephrosis	1	(0.8)		
Renal colic			1	(0.8)
Ureterolithiasis			1	(0.8)
Reproductive system and breast disorders				
Acquired phimosis	1	(0.8)		
Polycystic ovaries	1	(0.8)		
Ovarian cyst			1	(0.8)
Varicocele			1	(0.8)
Respiratory, thoracic and mediastinal disorders				
Asthma	2	(1.5)		

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Table 1.3.103.4.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=18 and < 65)				
Respiratory, thoracic and mediastinal disorders				
Asthma			8	(6.1)
Rhinitis allergic	2	(1.5)	1	(0.8)
Maxillary sinus pseudocyst	1	(0.8)		
Bronchospasm			1	(0.8)
Pneumothorax			1	(0.8)
Skin and subcutaneous tissue disorders				
Dermatitis contact	2	(1.5)	1	(0.8)
Alopecia			2	(1.5)
Acne	1	(0.8)	1	(0.8)
Acne conglobata	1	(0.8)		
Dermal cyst	1	(0.8)		
Dermatitis exfoliative	1	(0.8)		
Alopecia areata			1	(0.8)
Angioedema			1	(0.8)
Hidradenitis			1	(0.8)
Ingrowing nail			1	(0.8)
Purpura			1	(0.8)
Seborrhoeic dermatitis			1	(0.8)
Surgical and medical procedures				
Tonsillectomy	1	(0.8)	9	(6.8)
Adenoidectomy	3	(2.3)	2	(1.5)
Appendicectomy	3	(2.3)	3	(2.3)
Cholecystectomy	3	(2.3)	1	(0.8)
Ligament operation	3	(2.3)	2	(1.5)
Caesarean section	2	(1.5)	3	(2.3)
Immunisation	2	(1.5)		
Nasal septal operation	2	(1.5)	1	(0.8)
Abscess drainage			2	(1.5)
Arthrodesis			2	(1.5)
Cataract operation			2	(1.5)
Cyst removal	1	(0.8)	2	(1.5)
Hysterectomy	1	(0.8)	2	(1.5)
Knee operation			2	(1.5)
Turbinoplasty	1	(0.8)	2	(1.5)
UV light therapy			2	(1.5)
Benign tumour excision	1	(0.8)		
Cardiac ablation	1	(0.8)		
Carpal tunnel decompression	1	(0.8)	1	(0.8)
Endometrial ablation	1	(0.8)		
Eye laser surgery	1	(0.8)		
Finger amputation	1	(0.8)		
Hernia repair	1	(0.8)		
In vitro fertilisation	1	(0.8)		
Inguinal hernia repair	1	(0.8)	1	(0.8)
Jaw operation	1	(0.8)		
Keratoplasty	1	(0.8)		
Large intestinal polypectomy	1	(0.8)		
Meniscus operation	1	(0.8)	1	(0.8)
Myringotomy	1	(0.8)		
Oral surgery	1	(0.8)		
Ovarian cystectomy	1	(0.8)		
Pneumococcal immunisation	1	(0.8)		
Polypectomy	1	(0.8)		
Prophylaxis	1	(0.8)		
Shoulder operation	1	(0.8)		
Sinus operation	1	(0.8)		
Small intestinal resection	1	(0.8)		
Strabismus correction	1	(0.8)		
Tooth extraction	1	(0.8)	1	(0.8)
Tumour excision	1	(0.8)		
Ventriculo-peritoneal shunt	1	(0.8)		
Wisdom teeth removal	1	(0.8)		

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Table 1.3.103.4.1: Total, Age (>=18 and < 65), Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Age (>=18 and < 65)				
Surgical and medical procedures				
Wisdom teeth removal			1	(0.8)
Adrenalectomy			1	(0.8)
Amygdalotomy			1	(0.8)
Bunion operation			1	(0.8)
Cervical conisation			1	(0.8)
Circumcision			1	(0.8)
Eye operation			1	(0.8)
Female genital operation			1	(0.8)
Female sterilisation			1	(0.8)
Fracture treatment			1	(0.8)
Hepatitis B immunisation			1	(0.8)
Hospitalisation			1	(0.8)
Lip lesion excision			1	(0.8)
Meniscus removal			1	(0.8)
Myopia correction			1	(0.8)
Nasal polypectomy			1	(0.8)
Nephrectomy			1	(0.8)
Pleurodesis			1	(0.8)
Skin neoplasm excision			1	(0.8)
Thyroidectomy			1	(0.8)
Vascular disorders				
Hypertension	1	(0.8)		
Thrombophlebitis	1	(0.8)	1	(0.8)
Infarction			1	(0.8)

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Table 1.3.103.4.1: Total, Age (>=65), Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Age (>=65)				
Analysis set				
N	6		6	
Cardiac disorders				
Bundle branch block left	1	(16.7)		
Eye disorders				
Cataract	1	(16.7)	1	(16.7)
Infections and infestations				
Appendicitis	1	(16.7)		
Erysipelas			1	(16.7)
Herpes simplex			1	(16.7)
Herpes zoster			1	(16.7)
Injury, poisoning and procedural complications				
Multiple fractures	1	(16.7)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Basal cell carcinoma	1	(16.7)		
Bladder transitional cell carcinoma			1	(16.7)
Prostate cancer	1	(16.7)		
Squamous cell carcinoma of skin	1	(16.7)		
Psychiatric disorders				
Drug use disorder	1	(16.7)		
Reproductive system and breast disorders				
Breast cyst	1	(16.7)		
Sexual dysfunction			1	(16.7)
Respiratory, thoracic and mediastinal disorders				
Pulmonary embolism			1	(16.7)
Skin and subcutaneous tissue disorders				
Rosacea	1	(16.7)		
Surgical and medical procedures				
Appendicectomy	1	(16.7)		
Caesarean section	1	(16.7)		
Cataract operation			1	(16.7)
Hysterectomy	1	(16.7)	1	(16.7)
Nephrectomy			1	(16.7)
Oophorectomy			1	(16.7)
Spinal operation	1	(16.7)		
Stent placement	1	(16.7)		
Varicose vein operation	1	(16.7)		

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Table 1.3.104.3.1: Total, Age (>=18 and < 65), Atopy history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	236 (100.0)	118 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	55 (23.3)	24 (20.3)
1-3	21 (8.9)	6 (5.1)
More than 3	34 (14.4)	18 (15.3)
Never	140 (59.3)	77 (65.3)
Past	34 (14.4)	10 (8.5)
1-3	21 (8.9)	6 (5.1)
More than 3	13 (5.5)	4 (3.4)
Unknown	7 (3.0)	7 (5.9)
ASTHMA		
Current	115 (48.7)	53 (44.9)
Never	93 (39.4)	47 (39.8)
Past	27 (11.4)	18 (15.3)
Unknown	1 (0.4)	
ATOPIC KERATOCONJUNCTIVITIS		
Current	8 (3.4)	4 (3.4)
1-3	6 (2.5)	
More than 3	2 (0.8)	4 (3.4)
Never	216 (91.5)	103 (87.3)
Past	2 (0.8)	4 (3.4)
1-3	2 (0.8)	3 (2.5)
More than 3		1 (0.8)
Unknown	10 (4.2)	7 (5.9)
ECZEMA HERPETICUM		
Current	1 (0.4)	1 (0.8)
1-3	1 (0.4)	
More than 3		1 (0.8)
Never	204 (86.4)	104 (88.1)
Past	23 (9.7)	9 (7.6)
1-3	18 (7.6)	8 (6.8)
More than 3	5 (2.1)	1 (0.8)
Unknown	8 (3.4)	4 (3.4)
FOOD ALLERGY		
Current	87 (36.9)	46 (39.0)
Never	131 (55.5)	63 (53.4)
Past	9 (3.8)	3 (2.5)
Unknown	9 (3.8)	6 (5.1)
HAY FEVER		
Current	131 (55.5)	63 (53.4)
Never	85 (36.0)	48 (40.7)
Past	17 (7.2)	3 (2.5)
Unknown	3 (1.3)	4 (3.4)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.3.104.3.1: Total, Age (>=65), Atopy history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	16 (100.0)	8 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	3 (18.8)	2 (25.0)
More than 3	3 (18.8)	2 (25.0)
Never	8 (50.0)	5 (62.5)
Past		1 (12.5)
More than 3		1 (12.5)
Unknown	5 (31.3)	
ASTHMA		
Current	4 (25.0)	5 (62.5)
Never	11 (68.8)	3 (37.5)
Past	1 (6.3)	
ATOPIC KERATOCONJUNCTIVITIS		
Current		1 (12.5)
1-3		1 (12.5)
Never	12 (75.0)	7 (87.5)
Unknown	4 (25.0)	
ECZEMA HERPETICUM		
Never	14 (87.5)	8 (100.0)
Unknown	2 (12.5)	
FOOD ALLERGY		
Current	2 (12.5)	2 (25.0)
Never	14 (87.5)	6 (75.0)
HAY FEVER		
Current	10 (62.5)	5 (62.5)
Never	3 (18.8)	3 (37.5)
Unknown	3 (18.8)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.3.104.4.1: Total, Age (>=18 and < 65), Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	132 (100.0)	131 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	41 (31.1)	40 (30.5)
More than 3	24 (18.2)	29 (22.1)
Never	67 (50.8)	71 (54.2)
Past	21 (15.9)	19 (14.5)
More than 3	12 (9.1)	12 (9.2)
Unknown	3 (2.3)	1 (0.8)
ASTHMA		
Current	61 (46.2)	73 (55.7)
Never	58 (43.9)	53 (40.5)
Past	13 (9.8)	5 (3.8)
ATOPIC KERATOCONJUNCTIVITIS		
Current		9 (6.9)
More than 3		5 (3.8)
Never	125 (94.7)	111 (84.7)
Past	4 (3.0)	9 (6.9)
More than 3		3 (2.3)
Unknown	3 (2.3)	2 (1.5)
ECZEMA HERPETICUM		
Never	115 (87.1)	112 (85.5)
Past	14 (10.6)	15 (11.5)
More than 3	4 (3.0)	3 (2.3)
Unknown	3 (2.3)	4 (3.1)
FOOD ALLERGY		
Current	56 (42.4)	53 (40.5)
Never	72 (54.5)	74 (56.5)
Past	2 (1.5)	2 (1.5)
Unknown	2 (1.5)	2 (1.5)
HAY FEVER		
Current	74 (56.1)	74 (56.5)
Never	48 (36.4)	49 (37.4)
Past	9 (6.8)	5 (3.8)
Unknown	1 (0.8)	3 (2.3)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.3.104.4.1: Total, Age (>=65), Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	6 (100.0)	6 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current		1 (16.7)
Never	5 (83.3)	3 (50.0)
Past	1 (16.7)	2 (33.3)
ASTHMA		
Current	1 (16.7)	1 (16.7)
Never	5 (83.3)	5 (83.3)
ATOPIC KERATOCONJUNCTIVITIS		
Never	6 (100.0)	6 (100.0)
ECZEMA HERPETICUM		
Never	6 (100.0)	6 (100.0)
FOOD ALLERGY		
Current		2 (33.3)
Never	6 (100.0)	3 (50.0)
Unknown		1 (16.7)
HAY FEVER		
Current	2 (33.3)	3 (50.0)
Never	3 (50.0)	3 (50.0)
Past	1 (16.7)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.3.105.3.1: Total, Age (>=18 and < 65), Skin disease history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	236 (100.0)	118 (100.0)
ALOPECIA		
Current	10 (4.2)	8 (6.8)
Never	221 (93.6)	107 (90.7)
Past	4 (1.7)	1 (0.8)
Unknown	1 (0.4)	2 (1.7)
CELLULITIS		
Never	219 (92.8)	110 (93.2)
Past	12 (5.1)	6 (5.1)
1-3	11 (4.7)	5 (4.2)
More than 3	1 (0.4)	1 (0.8)
Unknown	5 (2.1)	2 (1.7)
HERPES SIMPLEX		
Current	11 (4.7)	8 (6.8)
1-3	5 (2.1)	2 (1.7)
More than 3	6 (2.5)	6 (5.1)
Never	171 (72.5)	92 (78.0)
Past	49 (20.8)	16 (13.6)
1-3	31 (13.1)	11 (9.3)
More than 3	18 (7.6)	5 (4.2)
Unknown	5 (2.1)	2 (1.7)
IMPETIGO		
Never	187 (79.2)	100 (84.7)
Past	36 (15.3)	12 (10.2)
1-3	26 (11.0)	8 (6.8)
More than 3	10 (4.2)	4 (3.4)
Unknown	13 (5.5)	6 (5.1)
OTHER SKIN INFECTIONS		
Never	202 (85.6)	97 (82.2)
Past	25 (10.6)	12 (10.2)
Unknown	9 (3.8)	9 (7.6)
VITILIGO		
Current	3 (1.3)	4 (3.4)
Never	231 (97.9)	114 (96.6)
Past	1 (0.4)	
Unknown	1 (0.4)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.3.105.3.1: Total, Age (>=65), Skin disease history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	16 (100.0)	8 (100.0)
ALOPECIA		
Never	16 (100.0)	8 (100.0)
CELLULITIS		
Never	16 (100.0)	8 (100.0)
HERPES SIMPLEX		
Never	14 (87.5)	7 (87.5)
Past	2 (12.5)	1 (12.5)
1-3	1 (6.3)	1 (12.5)
More than 3	1 (6.3)	
IMPETIGO		
Never	14 (87.5)	7 (87.5)
Past	2 (12.5)	1 (12.5)
1-3	2 (12.5)	1 (12.5)
OTHER SKIN INFECTIONS		
Never	14 (87.5)	6 (75.0)
Past	2 (12.5)	2 (25.0)
VITILIGO		
Never	16 (100.0)	8 (100.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.3.105.4.1: Total, Age (>=18 and < 65), Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	132 (100.0)	131 (100.0)
ALOPECIA		
Current	2 (1.5)	5 (3.8)
Never	127 (96.2)	124 (94.7)
Past	2 (1.5)	1 (0.8)
Unknown	1 (0.8)	1 (0.8)
CELLULITIS		
Never	124 (93.9)	124 (94.7)
Past	3 (2.3)	7 (5.3)
Unknown	5 (3.8)	
HERPES SIMPLEX		
Current	14 (10.6)	11 (8.4)
More than 3	7 (5.3)	8 (6.1)
Never	87 (65.9)	86 (65.6)
Past	27 (20.5)	33 (25.2)
More than 3	11 (8.3)	22 (16.8)
Unknown	4 (3.0)	1 (0.8)
IMPETIGO		
Never	102 (77.3)	94 (71.8)
Past	27 (20.5)	35 (26.7)
More than 3	8 (6.1)	13 (9.9)
Unknown	3 (2.3)	2 (1.5)
OTHER SKIN INFECTIONS		
Never	112 (84.8)	111 (84.7)
Past	11 (8.3)	15 (11.5)
Unknown	9 (6.8)	5 (3.8)
VITILIGO		
Current	1 (0.8)	1 (0.8)
Never	129 (97.7)	130 (99.2)
Past	1 (0.8)	
Unknown	1 (0.8)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.3.105.4.1: Total, Age (>=65), Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	6 (100.0)	6 (100.0)
ALOPECIA		
Never	6 (100.0)	6 (100.0)
CELLULITIS		
Never	6 (100.0)	6 (100.0)
HERPES SIMPLEX		
Current		1 (16.7)
Never	5 (83.3)	3 (50.0)
Past	1 (16.7)	2 (33.3)
More than 3	1 (16.7)	1 (16.7)
IMPETIGO		
Never	6 (100.0)	5 (83.3)
Past		1 (16.7)
OTHER SKIN INFECTIONS		
Never	5 (83.3)	6 (100.0)
Past	1 (16.7)	
VITILIGO		
Never	6 (100.0)	6 (100.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.3.107.3.1: Total, Age (>=18 and < 65), Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	236 (100.0)	118 (100.0)
Antibiotics		
Yes	104 (44.1)	43 (36.4)
No	126 (53.4)	68 (57.6)
Unknown	6 (2.5)	7 (5.9)
Azathioprine		
Yes	13 (5.5)	12 (10.2)
More than 12 weeks?		
Yes	5 (2.1)	8 (6.8)
No	5 (2.1)	2 (1.7)
Unknown	3 (1.3)	2 (1.7)
Reason for discontinuation		
Inadequate efficacy	9 (3.8)	9 (7.6)
Other	1 (0.4)	1 (0.8)
Side effects	3 (1.3)	2 (1.7)
No	218 (92.4)	104 (88.1)
Reason for not using		
Contraindications	3 (1.3)	1 (0.8)
Risk of side effects	25 (10.6)	16 (13.6)
Other	190 (80.5)	87 (73.7)
Unknown	5 (2.1)	2 (1.7)
Calcineurin inhibitors		
Yes	123 (52.1)	66 (55.9)
No	103 (43.6)	49 (41.5)
Unknown	9 (3.8)	3 (2.5)
Cyclosporine		
Yes	75 (31.8)	41 (34.7)
More than 12 weeks?		
Yes	60 (25.4)	33 (28.0)
No	13 (5.5)	4 (3.4)
Unknown	2 (0.8)	4 (3.4)
Reason for discontinuation		
Inadequate efficacy	42 (17.8)	19 (16.1)
Other	13 (5.5)	12 (10.2)
Side effects	19 (8.1)	10 (8.5)
No	153 (64.8)	72 (61.0)
Reason for not using		
Contraindications	13 (5.5)	2 (1.7)
Risk of side effects	43 (18.2)	28 (23.7)
Other	97 (41.1)	42 (35.6)
Unknown	8 (3.4)	5 (4.2)
Methotrexate		
Yes	27 (11.4)	29 (24.6)
More than 12 weeks?		
Yes	15 (6.4)	12 (10.2)
No	5 (2.1)	9 (7.6)
Unknown	7 (3.0)	8 (6.8)
Reason for discontinuation		
Inadequate efficacy	10 (4.2)	11 (9.3)
Other	11 (4.7)	13 (11.0)
Side effects	6 (2.5)	5 (4.2)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.107.3.1: Total, Age (>=18 and < 65), Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	202 (85.6)	88 (74.6)
Reason for not using		
Contraindications	4 (1.7)	1 (0.8)
Risk of side effects	18 (7.6)	10 (8.5)
Other	180 (76.3)	77 (65.3)
Unknown	7 (3.0)	1 (0.8)
Monoclonal antibody/Dupilumab		
Yes	14 (5.9)	9 (7.6)
No	219 (92.8)	107 (90.7)
Unknown	2 (0.8)	2 (1.7)
Mycophenolate		
Yes	7 (3.0)	5 (4.2)
More than 12 weeks?		
Yes	2 (0.8)	1 (0.8)
No	2 (0.8)	2 (1.7)
Unknown	3 (1.3)	2 (1.7)
Reason for discontinuation		
Inadequate efficacy	3 (1.3)	4 (3.4)
Other	1 (0.4)	1 (0.8)
Side effects	2 (0.8)	
No	219 (92.8)	109 (92.4)
Reason for not using		
Contraindications	3 (1.3)	1 (0.8)
Risk of side effects	23 (9.7)	16 (13.6)
Other	193 (81.8)	92 (78.0)
Unknown	10 (4.2)	4 (3.4)
Other immunosuppressant		
Yes	5 (2.1)	
No	226 (95.8)	114 (96.6)
Unknown	5 (2.1)	4 (3.4)
Phototherapy		
Yes	118 (50.0)	49 (41.5)
No	113 (47.9)	68 (57.6)
Unknown	5 (2.1)	1 (0.8)
Systemic steroids		
Yes	142 (60.2)	80 (67.8)
No	91 (38.6)	34 (28.8)
Unknown	3 (1.3)	4 (3.4)
Topical corticosteroids		
Yes	234 (99.2)	113 (95.8)
Highest potency		
High	120 (50.8)	53 (44.9)
Low	6 (2.5)	1 (0.8)
Moderate	46 (19.5)	27 (22.9)
Ultra high	52 (22.0)	27 (22.9)
Unknown	10 (4.2)	5 (4.2)
No	2 (0.8)	5 (4.2)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.107.3.1: Total, Age (>=18 and < 65), Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Wet wraps		
Yes	33 (14.0)	15 (12.7)
No	192 (81.4)	98 (83.1)
Unknown	11 (4.7)	5 (4.2)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.107.3.1: Total, Age (>=65), Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	16 (100.0)	8 (100.0)
Antibiotics		
Yes	3 (18.8)	1 (12.5)
No	12 (75.0)	6 (75.0)
Unknown	1 (6.3)	1 (12.5)
Azathioprine		
No	16 (100.0)	8 (100.0)
Reason for not using		
Contraindications		1 (12.5)
Risk of side effects	2 (12.5)	
Other	14 (87.5)	7 (87.5)
Calcineurin inhibitors		
Yes	4 (25.0)	2 (25.0)
No	11 (68.8)	5 (62.5)
Unknown	1 (6.3)	1 (12.5)
Cyclosporine		
Yes		1 (12.5)
More than 12 weeks?		
Yes		1 (12.5)
Reason for discontinuation		
Side effects		1 (12.5)
No	15 (93.8)	7 (87.5)
Reason for not using		
Contraindications	2 (12.5)	1 (12.5)
Risk of side effects	7 (43.8)	2 (25.0)
Other	6 (37.5)	4 (50.0)
Unknown	1 (6.3)	
Methotrexate		
Yes	2 (12.5)	1 (12.5)
More than 12 weeks?		
Yes	1 (6.3)	1 (12.5)
Unknown	1 (6.3)	
Reason for discontinuation		
Inadequate efficacy	1 (6.3)	
Other	1 (6.3)	1 (12.5)
No	14 (87.5)	7 (87.5)
Reason for not using		
Contraindications		1 (12.5)
Risk of side effects	1 (6.3)	
Other	13 (81.3)	6 (75.0)
Monoclonal antibody/Dupilumab		
Yes		1 (12.5)
No	16 (100.0)	7 (87.5)
Mycophenolate		
No	16 (100.0)	7 (87.5)
Reason for not using		
Contraindications		1 (12.5)
Risk of side effects	2 (12.5)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.107.3.1: Total, Age (>=65), Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Other	14 (87.5)	6 (75.0)
Unknown		1 (12.5)
Other immunosuppressant		
Yes	1 (6.3)	
No	15 (93.8)	7 (87.5)
Unknown		1 (12.5)
Phototherapy		
Yes	4 (25.0)	3 (37.5)
No	12 (75.0)	5 (62.5)
Systemic steroids		
Yes	5 (31.3)	5 (62.5)
No	9 (56.3)	3 (37.5)
Unknown	2 (12.5)	
Topical corticosteroids		
Yes	16 (100.0)	8 (100.0)
Highest potency		
High	11 (68.8)	4 (50.0)
Moderate	2 (12.5)	2 (25.0)
Ultra high	3 (18.8)	2 (25.0)
Wet wraps		
Yes	1 (6.3)	
No	14 (87.5)	7 (87.5)
Unknown	1 (6.3)	1 (12.5)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.107.4.1: Total, Age (>=18 and < 65), Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	132 (100.0)	131 (100.0)
Antibiotics		
Yes	54 (40.9)	65 (49.6)
No	72 (54.5)	57 (43.5)
Unknown	6 (4.5)	9 (6.9)
Azathioprine		
Yes	17 (12.9)	17 (13.0)
More than 12 weeks?		
Yes	12 (9.1)	11 (8.4)
No	4 (3.0)	3 (2.3)
Unknown	1 (0.8)	3 (2.3)
Reason for discontinuation		
Inadequate efficacy	11 (8.3)	13 (9.9)
Other	1 (0.8)	2 (1.5)
Side effects	5 (3.8)	2 (1.5)
No	109 (82.6)	111 (84.7)
Reason for not using		
Contraindications	5 (3.8)	8 (6.1)
Risk of side effects	42 (31.8)	31 (23.7)
Other	62 (47.0)	72 (55.0)
Unknown	6 (4.5)	3 (2.3)
Cyclosporine		
Yes	102 (77.3)	100 (76.3)
More than 12 weeks?		
Yes	68 (51.5)	70 (53.4)
No	34 (25.8)	29 (22.1)
Unknown		1 (0.8)
Reason for discontinuation		
Treatment duration >	5 (3.8)	7 (5.3)
Inadequate efficacy	49 (37.1)	43 (32.8)
Other	7 (5.3)	7 (5.3)
Side effects	41 (31.1)	43 (32.8)
No	30 (22.7)	31 (23.7)
Reason for not using		
Contraindications	24 (18.2)	22 (16.8)
Risk of side effects	4 (3.0)	3 (2.3)
Other	2 (1.5)	6 (4.6)
Methotrexate		
Yes	22 (16.7)	26 (19.8)
More than 12 weeks?		
Yes	14 (10.6)	18 (13.7)
No	8 (6.1)	7 (5.3)
Unknown		1 (0.8)
Reason for discontinuation		
Inadequate efficacy	14 (10.6)	18 (13.7)
Other	1 (0.8)	2 (1.5)
Side effects	7 (5.3)	6 (4.6)
No	108 (81.8)	103 (78.6)
Reason for not using		
Contraindications	11 (8.3)	11 (8.4)
Risk of side effects	37 (28.0)	28 (21.4)
Other	60 (45.5)	64 (48.9)
Unknown	2 (1.5)	2 (1.5)
Monoclonal antibody/Dupilumab		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.107.4.1: Total, Age (>=18 and < 65), Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	8 (6.1)	10 (7.6)
No	122 (92.4)	120 (91.6)
Unknown	2 (1.5)	1 (0.8)
Mycophenolate		
Yes	2 (1.5)	5 (3.8)
More than 12 weeks?		
Yes	2 (1.5)	1 (0.8)
No		4 (3.1)
Reason for discontinuation		
Inadequate efficacy	2 (1.5)	3 (2.3)
Side effects		2 (1.5)
No	122 (92.4)	123 (93.9)
Reason for not using		
Contraindications	4 (3.0)	6 (4.6)
Risk of side effects	43 (32.6)	31 (23.7)
Other	74 (56.1)	86 (65.6)
Unknown	8 (6.1)	3 (2.3)
Other immunosuppressant		
Yes	16 (12.1)	12 (9.2)
No	114 (86.4)	117 (89.3)
Unknown	2 (1.5)	2 (1.5)
Phototherapy		
Yes	76 (57.6)	81 (61.8)
No	55 (41.7)	50 (38.2)
Unknown	1 (0.8)	
Systemic steroids		
Yes	93 (70.5)	88 (67.2)
No	35 (26.5)	36 (27.5)
Unknown	4 (3.0)	7 (5.3)
Topical calcineurin inhibitor		
Yes	87 (65.9)	91 (69.5)
No	36 (27.3)	38 (29.0)
Unknown	9 (6.8)	2 (1.5)
Topical corticosteroids		
Yes	132 (100.0)	130 (99.2)
Highest potency		
High	71 (53.8)	49 (37.4)
Low		1 (0.8)
Moderate	10 (7.6)	14 (10.7)
Ultra high	42 (31.8)	63 (48.1)
Unknown	9 (6.8)	3 (2.3)
No		1 (0.8)
Wet wraps		
Yes	24 (18.2)	17 (13.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.107.4.1: Total, Age (>=18 and < 65), Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	99 (75.0)	110 (84.0)
Unknown	9 (6.8)	4 (3.1)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.107.4.1: Total, Age (>=65), Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	6 (100.0)	6 (100.0)
Antibiotics		
Yes	1 (16.7)	1 (16.7)
No	4 (66.7)	5 (83.3)
Unknown	1 (16.7)	
Azathioprine		
Yes	1 (16.7)	1 (16.7)
More than 12 weeks?		
Yes	1 (16.7)	1 (16.7)
Reason for discontinuation		
Inadequate efficacy	1 (16.7)	1 (16.7)
No	5 (83.3)	5 (83.3)
Reason for not using		
Contraindications		2 (33.3)
Risk of side effects	2 (33.3)	2 (33.3)
Other	3 (50.0)	1 (16.7)
Cyclosporine		
Yes	2 (33.3)	2 (33.3)
More than 12 weeks?		
Yes	2 (33.3)	1 (16.7)
No		1 (16.7)
Reason for discontinuation		
Inadequate efficacy	2 (33.3)	
Side effects		2 (33.3)
No	4 (66.7)	4 (66.7)
Reason for not using		
Contraindications	4 (66.7)	2 (33.3)
Risk of side effects		1 (16.7)
Other		1 (16.7)
Methotrexate		
Yes	1 (16.7)	
More than 12 weeks?		
Yes	1 (16.7)	
Reason for discontinuation		
Inadequate efficacy	1 (16.7)	
No	5 (83.3)	6 (100.0)
Reason for not using		
Contraindications		1 (16.7)
Risk of side effects	2 (33.3)	4 (66.7)
Other	3 (50.0)	1 (16.7)
Monoclonal antibody/Dupilumab		
Yes	1 (16.7)	2 (33.3)
No	5 (83.3)	4 (66.7)
Mycophenolate		
Yes	1 (16.7)	
More than 12 weeks?		
Yes	1 (16.7)	
Reason for discontinuation		
Inadequate efficacy	1 (16.7)	
No	5 (83.3)	6 (100.0)
Reason for not using		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.107.4.1: Total, Age (>=65), Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Contraindications		2 (33.3)
Risk of side effects	2 (33.3)	3 (50.0)
Other	3 (50.0)	1 (16.7)
Other immunosuppressant		
No	6 (100.0)	6 (100.0)
Phototherapy		
Yes	3 (50.0)	3 (50.0)
No	3 (50.0)	3 (50.0)
Systemic steroids		
Yes	4 (66.7)	3 (50.0)
No	1 (16.7)	3 (50.0)
Unknown	1 (16.7)	
Topical calcineurin inhibitor		
Yes	5 (83.3)	4 (66.7)
No	1 (16.7)	2 (33.3)
Topical corticosteroids		
Yes	6 (100.0)	6 (100.0)
Highest potency		
High	5 (83.3)	5 (83.3)
Moderate		1 (16.7)
Ultra high	1 (16.7)	
Wet wraps		
Yes	1 (16.7)	2 (33.3)
No	5 (83.3)	4 (66.7)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.3.205.3.1: Total, Age group, EASI 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	141 (56.0)	20.2 (9.77;30.56)	1.6 (1.21; 2.03)	2.3 (1.46; 3.53)	0.0002	0.8218
Placebo + TCS	126	45 (35.7)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	236	131 (55.5)	19.9 (9.20;30.69)	1.6 (1.19; 2.04)	2.3 (1.43; 3.55)	0.0004	
Placebo + TCS	118	42 (35.6)					
Age (>=65)							
Tralokinumab Q2W + TCS	16	10 (62.5)	27.1 (-12.3;66.51)	1.7 (0.69; 4.33)	3.7 (0.47;28.84)	0.2504	
Placebo + TCS	8	3 (37.5)					

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. #: 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 1.3.206.3.1: Total, Age group, EASI 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	83 (32.9)	11.4 (2.13;20.71)	1.5 (1.05; 2.25)	1.8 (1.08; 2.92)	0.0216	0.3284
Placebo + TCS	126	27 (21.4)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	236	78 (33.1)	12.7 (3.21;22.13)	1.6 (1.09; 2.43)	1.9 (1.14; 3.24)	0.0134	
Placebo + TCS	118	24 (20.3)					
Age (>=65)							
Tralokinumab Q2W + TCS	16	5 (31.3)	-6.8 (-52.8;39.26)	0.8 (0.21; 3.16)	0.8 (0.14; 4.25)	0.7738	
Placebo + TCS	8	3 (37.5)					

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. #: 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.

11FEB21 11:18 LP0162-Payer /p_bin_eff1/T_t_agr2_e06_39_w16.txt

Table 1.3.209.3.1: Total, Age group, SCORAD 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	60 (23.8)	11.1 (3.16;18.98)	1.9 (1.12; 3.12)	2.1 (1.17; 3.84)	0.0117	0.8169
Placebo + TCS	126	16 (12.7)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	236	57 (24.2)	11.4 (3.29;19.59)	1.9 (1.12; 3.23)	2.2 (1.17; 4.04)	0.0120	
Placebo + TCS	118	15 (12.7)					
Age (>=65)							
Tralokinumab Q2W + TCS	16	3 (18.8)	3.4 (-30.7;37.51)	1.2 (0.16; 9.29)	1.3 (0.13;12.45)	0.8417	
Placebo + TCS	8	1 (12.5)					

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. #: 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 1.3.210.3.1: Total, Age group, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	249	115 (46.2)	9.7 (-0.74;20.16)	1.3 (0.97; 1.65)	1.5 (0.96; 2.32)	0.0738	0.6458
Placebo + TCS	126	46 (36.5)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	233	109 (46.8)	10.3 (-0.49;21.09)	1.3 (0.97; 1.69)	1.5 (0.97; 2.41)	0.0670	
Placebo + TCS	118	43 (36.4)					
Age (>=65)							
Tralokinumab Q2W + TCS	16	6 (37.5)	-1.7 (-47.0;43.63)	1.0 (0.27; 3.37)	0.9 (0.17; 5.25)	0.9438	
Placebo + TCS	8	3 (37.5)					

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 1.3.211.3.1: Total, Age group, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	251	153 (61.0)	17.4 (6.78;27.98)	1.4 (1.12; 1.74)	2.0 (1.30; 3.10)	0.0014	0.4905
Placebo + TCS	126	55 (43.7)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	235	142 (60.4)	16.3 (5.38;27.28)	1.4 (1.09; 1.72)	1.9 (1.23; 3.02)	0.0037	
Placebo + TCS	118	52 (44.1)					
Age (>=65)							
Tralokinumab Q2W + TCS	16	11 (68.8)	27.1 (-19.5;73.78)	1.7 (0.57; 5.20)	2.6 (0.50;13.51)	0.2504	
Placebo + TCS	8	3 (37.5)					

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 1.3.213.3.1: Total, Age group, POEM improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	250	199 (79.6)	16.2 (6.28;26.17)	1.3 (1.08; 1.46)	2.2 (1.38; 3.58)	0.0008	0.6573
Placebo + TCS	123	78 (63.4)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	234	186 (79.5)	16.8 (6.51;27.16)	1.3 (1.09; 1.48)	2.3 (1.40; 3.72)	0.0008	
Placebo + TCS	115	72 (62.6)					
Age (>=65)							
Tralokinumab Q2W + TCS	16	13 (81.3)	1.7 (-37.5;40.90)	1.0 (0.65; 1.61)	1.1 (0.15; 8.11)	0.9282	
Placebo + TCS	8	6 (75.0)					

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.

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Table 1.3.215.3.1: Total, Age group, DLQI 0/1, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	62 (24.6)	12.7 (4.92;20.47)	2.1 (1.23; 3.47)	2.4 (1.31; 4.43)	0.0040	0.6138
Placebo + TCS	126	15 (11.9)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	236	56 (23.7)	11.9 (3.87;19.88)	2.0 (1.16; 3.43)	2.3 (1.22; 4.32)	0.0086	
Placebo + TCS	118	14 (11.9)					
Age (>=65)							
Tralokinumab Q2W + TCS	16	6 (37.5)	25.4 (-9.79;60.64)	2.7 (0.52;13.73)	4.0 (0.43;37.05)	0.2205	
Placebo + TCS	8	1 (12.5)					

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. #: 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 1.3.273.3.1: Total, Age group, SCORAD 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	21 (8.3)	2.0 (-3.46; 7.39)	1.3 (0.60; 2.85)	1.3 (0.57; 3.14)	0.4989	0.2343
Placebo + TCS	126	8 (6.3)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	236	19 (8.1)	1.3 (-4.33; 6.99)	1.2 (0.54; 2.65)	1.2 (0.51; 2.90)	0.6567	
Placebo + TCS	118	8 (6.8)					
Age (>=65)							
Tralokinumab Q2W + TCS	16	2 (12.5)	11.9 (-4.95;28.68)			0.3621	
Placebo + TCS	8	0 (0.0)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

Table 1.3.276.3.1: Total, Age group, Atopic dermatitis flares, all observed data, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	75.03	70 (27.8)	119	158.60	130.5	187.5	0.8999
Placebo + TCS	126	37.94	43 (34.1)	75	197.67	155.0	244.4	0.8999
Age (>=18 and < 65)								
Tralokinumab Q2W + TCS	236	70.15	67 (28.4)	112	159.67	131.7	191.0	
Placebo + TCS	118	35.64	40 (33.9)	71	199.20	156.9	250.0	
Age (>=65)								
Tralokinumab Q2W + TCS	16	4.89	3 (18.8)	7	143.21	18.3	244.8	
Placebo + TCS	8	2.30	3 (37.5)	4	174.01	12.6	264.9	

The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. 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. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.3.277.3.1: Total, Age group, Atopic dermatitis flares, excluding data after rescue medication, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	74.09	69 (27.4)	113	152.51	125.2	181.5	0.8601
Placebo + TCS	126	35.55	40 (31.7)	62	174.42	135.0	222.4	0.8601
Age (>=18 and < 65)								
Tralokinumab Q2W + TCS	236	69.32	66 (28.0)	107	154.36	126.9	185.6	
Placebo + TCS	118	33.31	37 (31.4)	59	177.12	137.2	228.6	
Age (>=65)								
Tralokinumab Q2W + TCS	16	4.77	3 (18.8)	6	125.67	17.8	242.2	
Placebo + TCS	8	2.23	3 (37.5)	3	134.27	9.8	249.1	

The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. 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. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.3.279.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)										
Total										
Baseline	126	126	7.9 (1.49)		252	251	7.7 (1.51)			
Week 16		112	4.7 (2.59)			226	3.5 (2.21)			
Week 16 chg		112	-3.1 (2.51)	-3.03 (0.21)		226	-4.1 (2.42)	-4.13 (0.15)	-1.10 (-1.61, -0.58) [-0.45 (-0.68, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7822
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.279.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)											
Baseline	118	118	7.9 (1.48)			236	235	7.7 (1.51)			
Week 16		105	4.7 (2.59)				211	3.5 (2.23)			
Week 16 chg		105	-3.1 (2.51)	-3.03	(0.22)		211	-4.1 (2.44)	-4.12	(0.16)	-1.08 (-1.62, -0.54) <.001 [-0.44 (-0.68, -0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7822
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.279.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 7.7 (1.72)		16	16 7.3 (1.57)		
Week 16		7 4.3 (2.78)			15 3.0 (1.82)		
Week 16 chg		7 -3.0 (2.60)	-3.04 (0.82)		15 -4.2 (2.04)	-4.23 (0.56)	-1.19 (-3.30, 0.93) 0.252 [-0.53 (-1.45, 0.38)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7822
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.280.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)			
Week 16		112 3.7 (2.86)			226 2.4 (2.25)			
Week 16 chg		112 -3.3 (2.59)	-3.23 (0.22)		226 -4.4 (2.62)	-4.42 (0.15)	-1.19 (-1.72, -0.67) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8927
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.280.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	118	118 7.1 (2.21)		236	235 7.0 (2.12)			
Week 16		105 3.7 (2.87)			211 2.4 (2.27)			
Week 16 chg		105 -3.3 (2.58)	-3.27 (0.23)		211 -4.4 (2.65)	-4.44 (0.16)	-1.16 (-1.71, -0.62) [-0.44 (-0.68, -0.21)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8927
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.280.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 7.1 (2.22)		16	16 6.2 (2.20)		
Week 16		7 4.0 (2.92)			15 2.4 (1.99)		
Week 16 chg		7 -2.7 (2.84)	-2.62 (0.88)		15 -4.1 (2.32)	-4.13 (0.61)	-1.51 (-3.78, 0.76) 0.179 [-0.61 (-1.52, 0.31)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8927
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.281.3.1: Total, Age group, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
SCORAD Score								
Total								
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)			
Week 16		122 40.9 (23.52)			241 29.4 (18.62)			
Week 16 chg		122 -27.7 (22.50)	-26.93 (1.75)		241 -37.4 (19.31)	-37.74 (1.24)	-10.81 (-15.0, -6.58) [-0.53 (-0.75, -0.31)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9254
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.281.3.1: Total, Age group, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	118	118 68.7 (13.39)		236	236 67.3 (13.18)			
Week 16		115 40.7 (23.42)			226 29.5 (18.77)			
Week 16 chg		115 -27.8 (22.45)	-27.20 (1.80)		226 -37.5 (19.18)	-37.78 (1.28)	-10.58 (-14.9, -6.22) [-0.52 (-0.75, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9254
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.281.3.1: Total, Age group, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 70.9 (10.13)		16	16 62.1 (13.87)		
Week 16		7 44.2 (26.82)			15 27.0 (16.47)		
Week 16 chg		7 -26.1 (25.11)	-20.83 (8.04)		15 -35.6 (21.94)	-37.70 (5.42)	-16.86 (-37.7, 3.97) 0.106 [-0.74 (-1.66, 0.19)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9254
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.282.3.1: Total, Age group, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score								
Total								
Baseline	126	125 17.2 (7.15)		252	250 17.6 (7.07)			
Week 16		120 8.3 (7.27)			239 5.7 (6.00)			
Week 16 chg		119 -8.8 (7.09)	-8.95 (0.55)		237 -11.8 (7.57)	-11.74 (0.39)	-2.78 (-4.10, -1.47) [-0.38 (-0.60, -0.15)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5772
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.282.3.1: Total, Age group, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	118	117 17.3 (7.03)		236	234 17.9 (7.01)			
Week 16		113 8.5 (7.37)			224 5.8 (6.10)			
Week 16 chg		112 -8.7 (7.15)	-9.01 (0.57)		222 -12.1 (7.62)	-11.91 (0.41)	-2.90 (-4.28, -1.52) [-0.39 (-0.62, -0.16)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5772
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.282.3.1: Total, Age group, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 16.1 (9.26)		16	16 12.3 (5.88)		
Week 16		7 5.3 (4.89)			15 3.7 (4.04)		
Week 16 chg		7 -9.1 (6.52)	-8.12 (1.60)		15 -8.7 (6.29)	-9.15 (1.10)	-1.03 (-5.17, 3.10) 0.606 [-0.16 (-1.06, 0.74)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5772
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.283.3.1: Total, Age group, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total										
Total										
Baseline	126	124	22.4 (5.63)		252	250	22.3 (5.09)			
Week 16		120	14.6 (8.22)			239	10.4 (7.20)			
Week 16 chg		118	-7.8 (7.40)	-7.74 (0.65)		237	-11.7 (7.37)	-11.74 (0.46)	-4.00 (-5.56, -2.44) [-0.54 (-0.77, -0.32)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5823
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.283.3.1: Total, Age group, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	118	116 22.4 (5.67)		236	234 22.6 (4.73)			
Week 16		113 14.7 (8.38)			224 10.7 (7.24)			
Week 16 chg		111 -7.7 (7.48)	-7.70 (0.68)		222 -11.8 (7.44)	-11.77 (0.48)	-4.06 (-5.70, -2.42) [-0.54 (-0.78, -0.31)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5823
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.283.3.1: Total, Age group, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 21.3 (5.12)		16	16 17.4 (7.47)		
Week 16		7 12.3 (4.82)			15 6.5 (5.26)		
Week 16 chg		7 -10.0 (5.94)	-7.55 (1.81)		15 -10.5 (6.38)	-11.54 (1.20)	-3.99 (-8.73, 0.74) 0.093 [-0.64 (-1.56, 0.28)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5823
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.285.3.1: Total, Age group, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score											
Total											
Baseline	126	125	59.4 (23.09)			252	250	59.1 (25.01)			
Week 16		117	71.5 (21.13)				234	75.8 (18.76)			
Week 16 chg		116	12.4 (22.66)	12.50	(1.65)		232	17.0 (24.19)	16.95	(1.17)	4.45 (0.46, 8.43) 0.029 [0.19 (-0.04, 0.41)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5998
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.285.3.1: Total, Age group, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)											
Baseline	118	117	58.5 (23.11)			236	234	58.3 (25.26)			
Week 16		110	71.0 (21.27)				219	75.3 (18.92)			
Week 16 chg		109	12.9 (22.51)	12.94	(1.71)		217	17.3 (24.30)	17.25	(1.22)	4.30 (0.17, 8.44) 0.041 [0.18 (-0.05, 0.41)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5998
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.285.3.1: Total, Age group, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 73.4 (18.97)		16	16 71.1 (17.43)		
Week 16		7 79.6 (18.27)			15 83.9 (14.41)		
Week 16 chg		7 4.3 (25.39)	6.71 (6.25)		15 13.3 (23.11)	12.31 (4.28)	5.60 (-10.6, 21.77) 0.475 [0.24 (-0.66, 1.14)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5998
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.286.3.1: Total, Age group, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	126	126 6.9 (2.72)		252	252 6.5 (2.77)		
Week 16		122 3.2 (3.24)			241 2.2 (2.68)		
Week 16 chg		122 -3.7 (3.20)	-3.44 (0.25)		241 -4.2 (3.34)	-4.29 (0.18)	-0.85 (-1.45, -0.25) 0.006 [-0.26 (-0.48, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.286.3.1: Total, Age group, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	118	118 6.9 (2.75)		236	236 6.5 (2.77)			
Week 16		115 3.1 (3.24)			226 2.2 (2.70)			
Week 16 chg		115 -3.7 (3.21)	-3.49 (0.26)		226 -4.2 (3.40)	-4.30 (0.18)	-0.81 (-1.43, -0.18) [-0.24 (-0.47, -0.02)]	0.012

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.286.3.1: Total, Age group, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 7.5 (2.39)		16	16 5.5 (2.65)		
Week 16		7 3.9 (3.38)			15 1.8 (2.34)		
Week 16 chg		7 -3.3 (3.32)	-2.88 (0.97)		15 -3.9 (2.29)	-4.14 (0.66)	-1.26 (-3.78, 1.27) 0.308 [-0.47 (-1.38, 0.43)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.291.3.1: Total, Age group, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	126	126 30.4 (12.78)		252	252 28.8 (11.97)		
Week 2		124 19.8 (12.98)			251 17.0 (11.25)		
Week 2 chg		124 -10.7 (11.46)	-10.25 (0.87)		251 -11.8 (10.37)	-12.03 (0.61)	-1.78 (-3.86, 0.30) 0.094 [-0.17 (-0.38, 0.05)]
Week 4		126 16.8 (13.62)			247 13.2 (10.47)		
Week 4 chg		126 -13.6 (12.25)	-13.09 (0.86)		247 -15.8 (11.28)	-15.88 (0.61)	-2.78 (-4.86, -0.70) 0.009 [-0.24 (-0.45, -0.02)]
Week 6		125 15.2 (13.41)			247 10.7 (9.46)		
Week 6 chg		125 -15.2 (12.09)	-14.70 (0.87)		247 -18.3 (11.21)	-18.31 (0.61)	-3.62 (-5.70, -1.53) <.001 [-0.31 (-0.53, -0.10)]
Week 8		122 13.6 (12.73)			243 9.3 (8.85)		
Week 8 chg		122 -16.7 (11.39)	-15.95 (0.87)		243 -19.8 (11.30)	-19.68 (0.61)	-3.73 (-5.82, -1.64) <.001 [-0.33 (-0.55, -0.11)]
Week 10		118 13.9 (13.56)			237 8.2 (8.42)		
Week 10 chg		118 -16.2 (11.61)	-15.71 (0.87)		237 -20.7 (12.01)	-20.64 (0.62)	-4.92 (-7.03, -2.82) <.001 [-0.41 (-0.64, -0.19)]
Week 12		119 12.9 (12.82)			238 8.0 (9.27)		
Week 12 chg		119 -17.2 (11.92)	-16.57 (0.87)		238 -21.1 (12.42)	-21.12 (0.62)	-4.55 (-6.65, -2.45) <.001 [-0.37 (-0.59, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6468
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 1.3.291.3.1: Total, Age group, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	13.1 (13.79)		235	7.7 (9.25)			
Week 14 chg	118	-16.9 (13.53)	-16.27 (0.87)	235	-21.4 (12.29)	-21.30 (0.62)	-5.03 (-7.14, -2.93) [-0.40 (-0.62, -0.17)]	<.001
Week 16	123	14.1 (14.89)		241	8.1 (9.15)			
Week 16 chg	123	-16.0 (14.04)	-15.45 (0.87)	241	-20.7 (12.33)	-20.92 (0.62)	-5.47 (-7.56, -3.38) [-0.42 (-0.64, -0.20)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6468
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 1.3.291.3.1: Total, Age group, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	118	118 30.3 (12.85)		236	236 29.0 (11.94)		
Week 2		116 19.7 (13.08)			235 17.2 (11.35)		
Week 2 chg		116 -10.7 (11.45)	-10.29 (0.89)		235 -11.8 (10.50)	-12.02 (0.63)	-1.74 (-3.88, 0.40) 0.111 [-0.16 (-0.38, 0.06)]
Week 4		118 17.0 (13.69)			231 13.3 (10.67)		
Week 4 chg		118 -13.3 (11.93)	-12.92 (0.89)		231 -15.9 (11.38)	-15.89 (0.63)	-2.97 (-5.10, -0.83) 0.007 [-0.26 (-0.48, -0.03)]
Week 6		117 15.0 (12.95)			231 10.7 (9.56)		
Week 6 chg		117 -15.3 (11.34)	-14.90 (0.89)		231 -18.5 (11.16)	-18.44 (0.63)	-3.55 (-5.69, -1.41) 0.001 [-0.32 (-0.54, -0.09)]
Week 8		114 13.7 (12.67)			227 9.2 (8.92)		
Week 8 chg		114 -16.5 (11.01)	-15.88 (0.89)		227 -20.0 (11.16)	-19.81 (0.63)	-3.93 (-6.08, -1.79) <.001 [-0.35 (-0.58, -0.13)]
Week 10		111 14.0 (13.52)			221 8.1 (8.44)		
Week 10 chg		111 -16.1 (11.40)	-15.55 (0.90)		221 -21.0 (11.74)	-20.83 (0.63)	-5.28 (-7.44, -3.12) <.001 [-0.45 (-0.68, -0.22)]
Week 12		112 13.0 (12.74)			222 7.9 (9.36)		
Week 12 chg		112 -17.0 (11.74)	-16.40 (0.89)		222 -21.4 (12.29)	-21.27 (0.63)	-4.87 (-7.03, -2.72) <.001 [-0.40 (-0.63, -0.17)]
Week 14		111 13.0 (13.55)			219 7.6 (9.26)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6468
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 1.3.291.3.1: Total, Age group, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	111	-17.0 (13.17)	-16.28 (0.90)	219	-21.5 (12.16)	-21.39 (0.64)	-5.12 (-7.28, -2.96) [-0.41 (-0.64, -0.18)]	<.001
Week 16	116	14.0 (14.80)		226	8.1 (9.21)			
Week 16 chg	116	-16.1 (13.80)	-15.46 (0.89)	226	-20.7 (12.25)	-20.99 (0.63)	-5.53 (-7.67, -3.39) [-0.43 (-0.66, -0.21)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6468
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 1.3.291.3.1: Total, Age group, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 32.0 (12.49)		16	16 26.7 (12.50)		
Week 2		8 20.6 (12.12)			16 15.2 (9.79)		
Week 2 chg		8 -11.4 (12.39)	-9.24 (4.00)		16 -11.5 (8.56)	-12.38 (2.79)	-3.15 (-13.3, 6.97) 0.529 [-0.32 (-1.17, 0.54)]
Week 4		8 14.2 (13.12)			16 11.9 (7.15)		
Week 4 chg		8 -17.8 (16.61)	-14.66 (4.00)		16 -14.9 (10.08)	-16.15 (2.79)	-1.49 (-11.6, 8.62) 0.765 [-0.12 (-0.97, 0.73)]
Week 6		8 17.9 (19.90)			16 11.2 (8.05)		
Week 6 chg		8 -14.1 (21.34)	-10.89 (4.00)		16 -15.6 (11.95)	-16.88 (2.79)	-5.99 (-16.1, 4.13) 0.235 [-0.38 (-1.24, 0.47)]
Week 8		8 12.6 (14.38)			16 9.8 (8.13)		
Week 8 chg		8 -19.4 (16.58)	-15.98 (4.00)		16 -16.9 (13.16)	-18.33 (2.79)	-2.35 (-12.5, 7.76) 0.638 [-0.16 (-1.01, 0.69)]
Week 10		7 12.2 (15.26)			16 9.8 (8.14)		
Week 10 chg		7 -18.1 (15.46)	-17.32 (4.05)		16 -16.9 (15.21)	-18.49 (2.79)	-1.17 (-11.4, 9.02) 0.817 [-0.08 (-0.96, 0.81)]
Week 12		7 11.2 (15.07)			16 8.8 (8.14)		
Week 12 chg		7 -19.1 (15.48)	-18.52 (4.05)		16 -18.0 (14.11)	-19.46 (2.79)	-0.93 (-11.1, 9.25) 0.853 [-0.06 (-0.95, 0.82)]
Week 14		7 14.3 (18.42)			16 7.7 (9.42)		

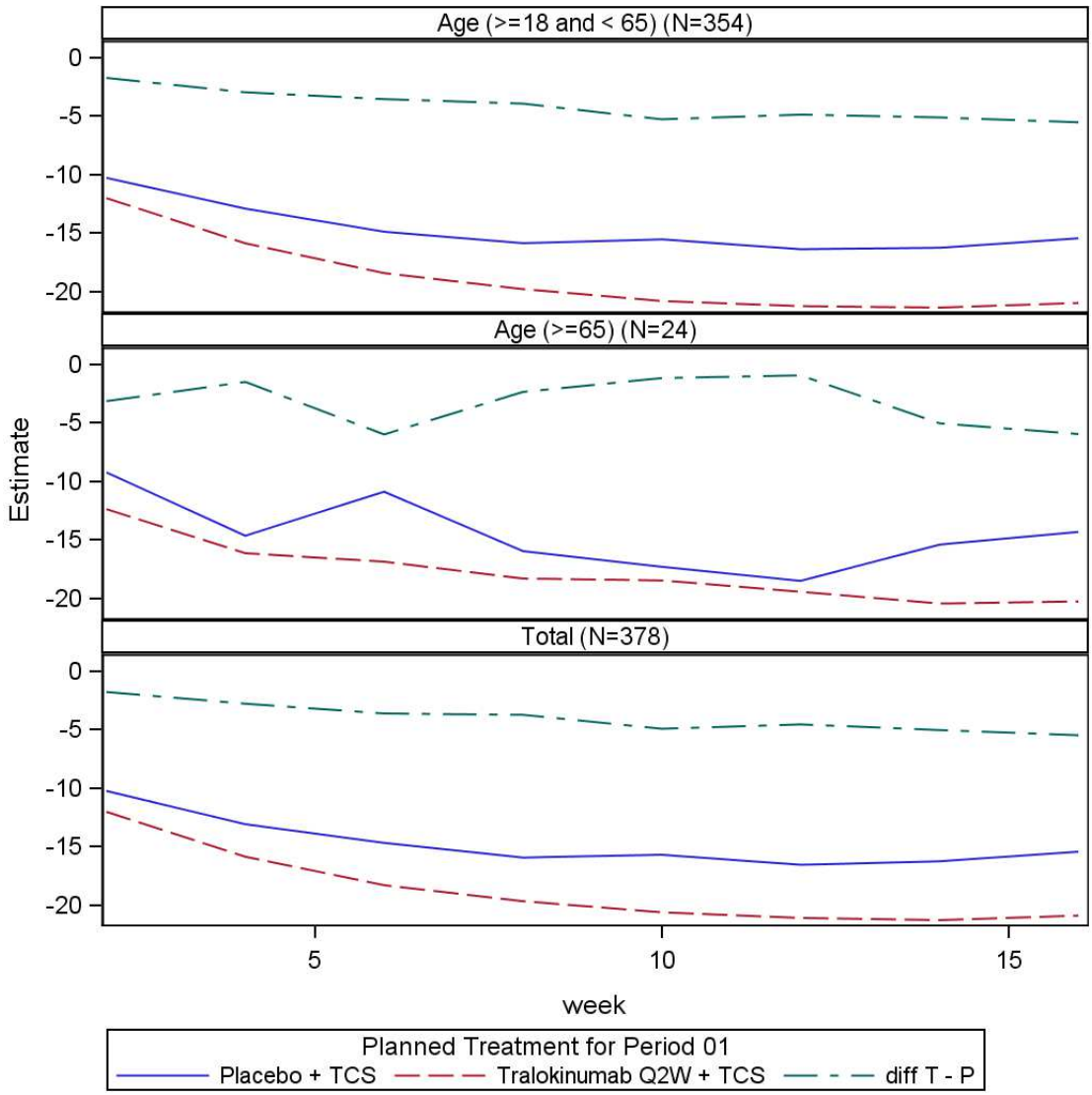
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6468
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.3.291.3.1: Total, Age group, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg		7 -16.0 (19.78)	-15.42 (4.05)		16 -19.0 (14.13)	-20.46 (2.79)	-5.04 (-15.2, 5.15) [-0.32 (-1.21, 0.58)]	0.320
Week 16		7 15.4 (17.62)			15 7.9 (8.48)			
Week 16 chg		7 -14.9 (18.77)	-14.33 (4.05)		15 -19.4 (13.89)	-20.29 (2.81)	-5.96 (-16.2, 4.24) [-0.38 (-1.29, 0.52)]	0.242

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6468
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 1.3.291.3.2: Total, Age group, change in EASI, Treatment policy estimand, LP0162-1339, 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 1.3.293.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)										
Total										
Baseline	126	126	7.9 (1.49)		252	251	7.7 (1.51)			
Week 1		125	6.5 (1.78)			248	6.2 (1.90)			
Week 1 chg		125	-1.3 (1.50)	-1.27 (0.19)		248	-1.5 (1.56)	-1.50 (0.14)	-0.23 (-0.69, 0.24) [-0.15 (-0.36, 0.07)]	0.336
Week 2		126	6.0 (2.11)			245	5.5 (2.23)			
Week 2 chg		126	-1.8 (2.00)	-1.80 (0.19)		245	-2.2 (2.02)	-2.19 (0.14)	-0.39 (-0.85, 0.07) [-0.19 (-0.41, 0.02)]	0.097
Week 3		125	5.8 (2.18)			243	5.0 (2.26)			
Week 3 chg		125	-2.0 (2.05)	-1.97 (0.19)		243	-2.6 (2.15)	-2.65 (0.14)	-0.68 (-1.15, -0.22) [-0.32 (-0.54, -0.11)]	0.004
Week 4		120	5.5 (2.39)			244	4.8 (2.29)			
Week 4 chg		120	-2.4 (2.21)	-2.31 (0.19)		244	-2.9 (2.21)	-2.92 (0.14)	-0.62 (-1.08, -0.15) [-0.28 (-0.50, -0.06)]	0.009
Week 5		118	5.2 (2.42)			238	4.5 (2.21)			
Week 5 chg		118	-2.7 (2.31)	-2.62 (0.19)		238	-3.2 (2.19)	-3.19 (0.14)	-0.56 (-1.03, -0.10) [-0.25 (-0.47, -0.03)]	0.018
Week 6		122	5.1 (2.50)			239	4.3 (2.23)			
Week 6 chg		122	-2.7 (2.39)	-2.68 (0.19)		239	-3.3 (2.26)	-3.30 (0.14)	-0.62 (-1.08, -0.15) [-0.27 (-0.49, -0.05)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7968
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 1.3.293.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	116	4.9 (2.48)		231	4.2 (2.27)			
Week 7 chg	116	-2.9 (2.41)	-2.79 (0.19)	231	-3.5 (2.29)	-3.47 (0.14)	-0.68 (-1.15, -0.22) [-0.29 (-0.52, -0.07)]	0.004
Week 8	116	4.9 (2.49)		227	4.0 (2.31)			
Week 8 chg	116	-2.9 (2.38)	-2.81 (0.19)	227	-3.6 (2.35)	-3.60 (0.14)	-0.79 (-1.26, -0.32) [-0.34 (-0.56, -0.11)]	<.001
Week 9	116	4.9 (2.53)		235	3.9 (2.24)			
Week 9 chg	116	-3.0 (2.35)	-2.88 (0.19)	235	-3.7 (2.31)	-3.75 (0.14)	-0.87 (-1.33, -0.40) [-0.37 (-0.60, -0.15)]	<.001
Week 10	114	4.8 (2.56)		235	3.8 (2.27)			
Week 10 chg	114	-3.0 (2.45)	-2.97 (0.19)	235	-3.8 (2.43)	-3.82 (0.14)	-0.85 (-1.31, -0.38) [-0.35 (-0.57, -0.12)]	<.001
Week 11	115	4.8 (2.54)		231	3.6 (2.19)			
Week 11 chg	115	-3.0 (2.48)	-2.96 (0.19)	231	-4.0 (2.39)	-4.03 (0.14)	-1.06 (-1.53, -0.60) [-0.44 (-0.67, -0.21)]	<.001
Week 12	115	4.7 (2.55)		234	3.7 (2.15)			
Week 12 chg	115	-3.1 (2.41)	-2.99 (0.19)	234	-3.9 (2.40)	-3.97 (0.14)	-0.98 (-1.45, -0.51) [-0.41 (-0.63, -0.18)]	<.001
Week 13	115	4.8 (2.53)		233	3.6 (2.19)			
Week 13 chg	115	-3.1 (2.37)	-3.00 (0.19)	233	-4.1 (2.44)	-4.12 (0.14)	-1.12 (-1.59, -0.65) [-0.46 (-0.69, -0.24)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7968
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 1.3.293.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	116	4.7 (2.57)		223	3.6 (2.20)			
Week 14 chg	116	-3.1 (2.42)	-3.00 (0.19)	223	-4.0 (2.49)	-4.05 (0.14)	-1.05 (-1.52, -0.58) [-0.43 (-0.65, -0.20)]	<.001
Week 15	114	4.8 (2.59)		225	3.5 (2.20)			
Week 15 chg	114	-3.0 (2.44)	-3.00 (0.19)	225	-4.1 (2.43)	-4.10 (0.14)	-1.10 (-1.57, -0.63) [-0.45 (-0.68, -0.22)]	<.001
Week 16	112	4.7 (2.59)		226	3.5 (2.21)			
Week 16 chg	112	-3.1 (2.51)	-2.99 (0.19)	226	-4.1 (2.42)	-4.12 (0.14)	-1.13 (-1.60, -0.66) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7968
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 1.3.293.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	118	118 7.9 (1.48)		236	235 7.7 (1.51)			
Week 1		117 6.5 (1.78)			232 6.2 (1.91)			
Week 1 chg		117 -1.3 (1.50)	-1.29 (0.20)		232 -1.5 (1.55)	-1.53 (0.14)	-0.24 (-0.72, 0.23) [-0.16 (-0.38, 0.06)]	0.318
Week 2		118 6.0 (2.15)			229 5.5 (2.25)			
Week 2 chg		118 -1.8 (1.99)	-1.80 (0.20)		229 -2.2 (2.02)	-2.22 (0.14)	-0.41 (-0.89, 0.06) [-0.21 (-0.43, 0.02)]	0.090
Week 3		117 5.9 (2.16)			227 5.0 (2.30)			
Week 3 chg		117 -2.0 (1.99)	-1.96 (0.20)		227 -2.7 (2.16)	-2.69 (0.14)	-0.73 (-1.21, -0.25) [-0.35 (-0.57, -0.12)]	0.003
Week 4		112 5.5 (2.37)			228 4.7 (2.33)			
Week 4 chg		112 -2.3 (2.13)	-2.31 (0.20)		228 -2.9 (2.22)	-2.96 (0.14)	-0.65 (-1.13, -0.17) [-0.30 (-0.52, -0.07)]	0.008
Week 5		110 5.2 (2.42)			223 4.5 (2.23)			
Week 5 chg		110 -2.6 (2.28)	-2.62 (0.20)		223 -3.2 (2.20)	-3.22 (0.14)	-0.61 (-1.09, -0.12) [-0.27 (-0.50, -0.04)]	0.014
Week 6		114 5.1 (2.49)			223 4.3 (2.25)			
Week 6 chg		114 -2.7 (2.36)	-2.70 (0.20)		223 -3.4 (2.25)	-3.32 (0.14)	-0.62 (-1.10, -0.14) [-0.27 (-0.50, -0.05)]	0.011
Week 7		108 4.9 (2.47)			215 4.1 (2.30)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7968
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 1.3.293.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	108	-2.9 (2.38)	-2.79 (0.20)	215	-3.5 (2.29)	-3.52 (0.14)	-0.73 (-1.21, -0.24) [-0.31 (-0.55, -0.08)]	0.003
Week 8	108	4.9 (2.48)		211	4.0 (2.34)			
Week 8 chg	108	-2.9 (2.37)	-2.83 (0.20)	211	-3.6 (2.34)	-3.63 (0.14)	-0.80 (-1.29, -0.32) [-0.34 (-0.58, -0.11)]	0.001
Week 9	109	4.9 (2.51)		219	3.9 (2.26)			
Week 9 chg	109	-3.0 (2.33)	-2.87 (0.20)	219	-3.8 (2.30)	-3.81 (0.14)	-0.94 (-1.43, -0.46) [-0.41 (-0.64, -0.18)]	<.001
Week 10	107	4.8 (2.56)		219	3.8 (2.28)			
Week 10 chg	107	-3.0 (2.46)	-2.98 (0.20)	219	-3.9 (2.42)	-3.86 (0.14)	-0.88 (-1.37, -0.40) [-0.36 (-0.60, -0.13)]	<.001
Week 11	108	4.8 (2.52)		216	3.6 (2.21)			
Week 11 chg	108	-3.1 (2.48)	-2.96 (0.20)	216	-4.1 (2.39)	-4.10 (0.14)	-1.13 (-1.62, -0.65) [-0.47 (-0.70, -0.24)]	<.001
Week 12	108	4.7 (2.55)		218	3.7 (2.16)			
Week 12 chg	108	-3.1 (2.41)	-2.99 (0.20)	218	-4.0 (2.40)	-4.04 (0.14)	-1.04 (-1.53, -0.56) [-0.44 (-0.67, -0.20)]	<.001
Week 13	108	4.8 (2.53)		217	3.5 (2.21)			
Week 13 chg	108	-3.1 (2.38)	-3.01 (0.20)	217	-4.2 (2.44)	-4.19 (0.14)	-1.18 (-1.66, -0.69) [-0.49 (-0.72, -0.25)]	<.001
Week 14	109	4.7 (2.58)		207	3.5 (2.22)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7968
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 1.3.293.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	-3.1 (2.43)	-3.00 (0.20)	207	-4.1 (2.49)	-4.11 (0.14)	-1.11 (-1.60, -0.63) [-0.45 (-0.69, -0.22)]	<.001
Week 15	107	4.8 (2.58)		210	3.5 (2.22)			
Week 15 chg	107	-3.0 (2.43)	-2.97 (0.20)	210	-4.1 (2.44)	-4.13 (0.14)	-1.16 (-1.65, -0.68) [-0.48 (-0.71, -0.24)]	<.001
Week 16	105	4.7 (2.59)		211	3.5 (2.23)			
Week 16 chg	105	-3.1 (2.51)	-2.98 (0.20)	211	-4.1 (2.44)	-4.11 (0.14)	-1.13 (-1.62, -0.65) [-0.46 (-0.70, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7968
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 1.3.293.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 7.7 (1.72)		16	16 7.3 (1.57)		
Week 1		8 6.5 (1.91)			16 6.3 (1.84)		
Week 1 chg		8 -1.2 (1.61)	-1.03 (0.77)		16 -1.0 (1.64)	-1.04 (0.54)	-0.00 (-1.94, 1.93) 0.997 [-0.00 (-0.85, 0.85)]
Week 2		8 5.9 (1.56)			16 5.6 (2.01)		
Week 2 chg		8 -1.9 (2.18)	-1.58 (0.77)		16 -1.7 (2.05)	-1.72 (0.54)	-0.14 (-2.08, 1.80) 0.884 [-0.07 (-0.92, 0.78)]
Week 3		8 5.3 (2.53)			16 5.2 (1.58)		
Week 3 chg		8 -2.4 (2.99)	-2.05 (0.77)		16 -2.1 (1.95)	-2.16 (0.54)	-0.12 (-2.06, 1.82) 0.903 [-0.05 (-0.90, 0.80)]
Week 4		8 5.2 (2.84)			16 5.0 (1.74)		
Week 4 chg		8 -2.5 (3.32)	-2.18 (0.77)		16 -2.4 (2.06)	-2.42 (0.54)	-0.24 (-2.18, 1.70) 0.804 [-0.09 (-0.94, 0.76)]
Week 5		8 4.8 (2.59)			15 4.7 (1.96)		
Week 5 chg		8 -3.0 (2.85)	-2.69 (0.77)		15 -2.4 (1.97)	-2.68 (0.54)	0.00 (-1.94, 1.95) 0.998 [0.00 (-0.86, 0.86)]
Week 6		8 5.0 (2.83)			16 4.4 (1.91)		
Week 6 chg		8 -2.7 (3.02)	-2.34 (0.77)		16 -2.9 (2.39)	-2.93 (0.54)	-0.60 (-2.54, 1.34) 0.534 [-0.23 (-1.08, 0.62)]
Week 7		8 4.7 (2.75)			16 4.6 (1.82)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7968
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 1.3.293.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	8	-3.0 (2.96)	-2.71 (0.77)	16	-2.8 (2.17)	-2.81 (0.54)	-0.10 (-2.04, 1.83) [-0.04 (-0.89, 0.81)]	0.913
Week 8	8	4.9 (2.91)		16	4.2 (1.94)			
Week 8 chg	8	-2.8 (2.70)	-2.54 (0.77)	16	-3.1 (2.48)	-3.15 (0.54)	-0.61 (-2.55, 1.33) [-0.24 (-1.09, 0.61)]	0.524
Week 9	7	4.4 (2.95)		16	4.5 (1.89)			
Week 9 chg	7	-3.0 (2.82)	-3.07 (0.78)	16	-2.9 (2.35)	-2.92 (0.54)	0.16 (-1.80, 2.11) [0.06 (-0.82, 0.95)]	0.870
Week 10	7	4.7 (2.75)		16	4.2 (2.12)			
Week 10 chg	7	-2.7 (2.47)	-2.82 (0.78)	16	-3.1 (2.62)	-3.16 (0.54)	-0.35 (-2.30, 1.60) [-0.14 (-1.02, 0.75)]	0.718
Week 11	7	4.5 (2.99)		15	4.4 (1.88)			
Week 11 chg	7	-2.8 (2.79)	-2.95 (0.78)	15	-2.8 (2.17)	-3.03 (0.54)	-0.08 (-2.04, 1.88) [-0.03 (-0.93, 0.86)]	0.934
Week 12	7	4.6 (2.88)		16	4.3 (1.90)			
Week 12 chg	7	-2.8 (2.50)	-2.90 (0.78)	16	-3.0 (2.38)	-3.04 (0.54)	-0.14 (-2.09, 1.82) [-0.06 (-0.95, 0.83)]	0.887
Week 13	7	4.7 (2.78)		16	4.2 (1.78)			
Week 13 chg	7	-2.7 (2.41)	-2.77 (0.78)	16	-3.1 (2.31)	-3.15 (0.54)	-0.38 (-2.33, 1.58) [-0.16 (-1.05, 0.73)]	0.696
Week 14	7	4.5 (2.74)		16	4.2 (1.82)			

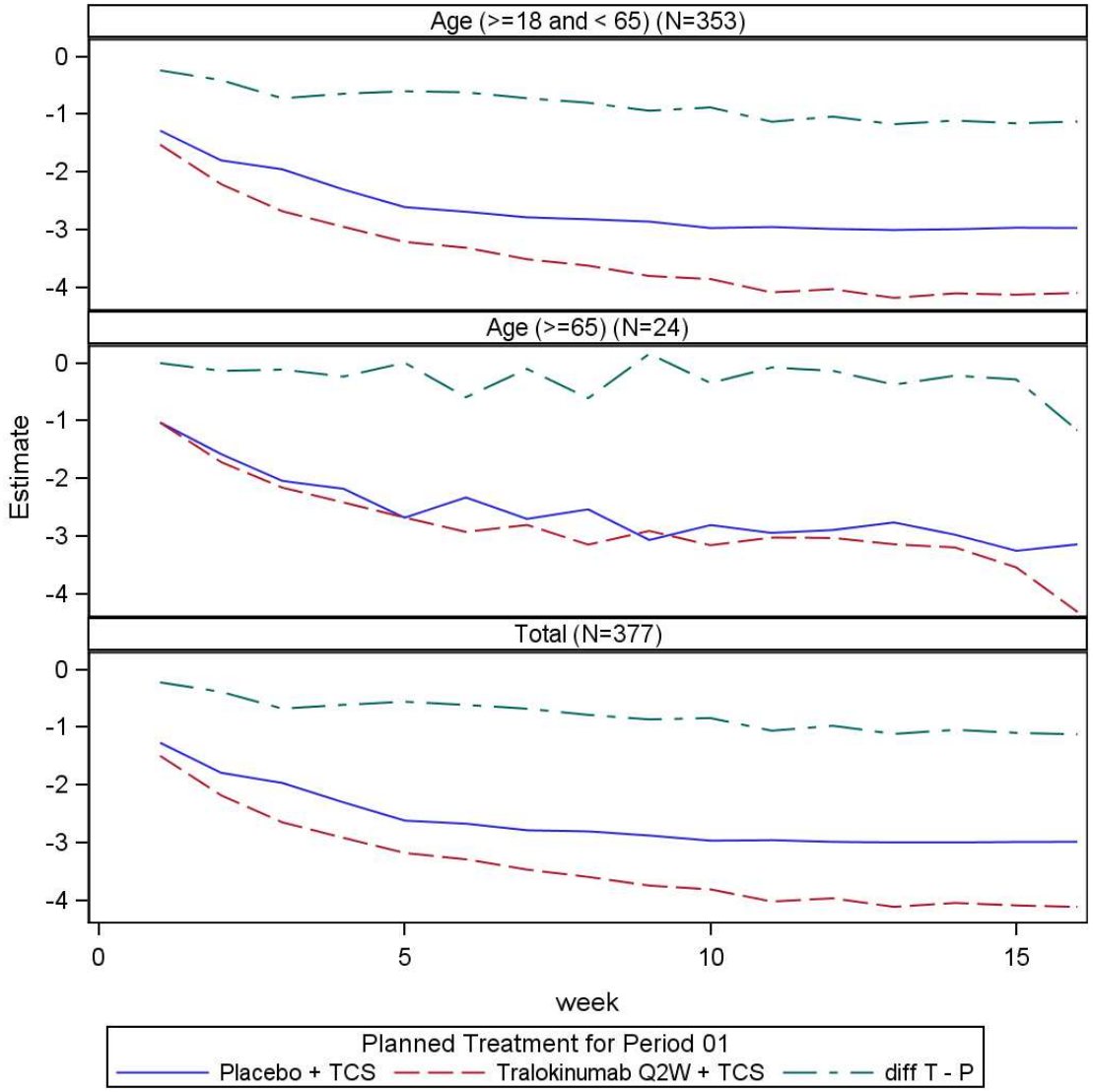
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7968
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.3.293.3.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	7	-2.9 (2.39)	-2.98 (0.78)	16	-3.1 (2.41)	-3.20 (0.54)	-0.22 (-2.18, 1.73) [-0.09 (-0.98, 0.80)]	0.819
Week 15	7	4.2 (2.83)		15	3.8 (1.89)			
Week 15 chg	7	-3.2 (2.66)	-3.26 (0.78)	15	-3.5 (2.25)	-3.55 (0.54)	-0.29 (-2.25, 1.67) [-0.12 (-1.02, 0.78)]	0.767
Week 16	7	4.3 (2.78)		15	3.0 (1.82)			
Week 16 chg	7	-3.0 (2.60)	-3.15 (0.78)	15	-4.2 (2.04)	-4.32 (0.54)	-1.17 (-3.13, 0.79) [-0.53 (-1.44, 0.38)]	0.232

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7968
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 1.3.293.3.2: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, 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 1.3.295.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)		
Week 1		125 5.7 (2.39)			248 5.3 (2.33)		
Week 1 chg		125 -1.4 (1.62)	-1.38 (0.20)		248 -1.6 (1.68)	-1.56 (0.14)	-0.18 (-0.65, 0.30) 0.468 [-0.11 (-0.32, 0.11)]
Week 2		126 5.1 (2.66)			245 4.5 (2.54)		
Week 2 chg		126 -1.9 (2.16)	-1.90 (0.20)		245 -2.4 (2.19)	-2.35 (0.14)	-0.45 (-0.93, 0.03) 0.066 [-0.21 (-0.42, 0.01)]
Week 3		125 4.9 (2.61)			243 4.0 (2.57)		
Week 3 chg		125 -2.2 (2.17)	-2.11 (0.20)		243 -2.9 (2.33)	-2.90 (0.14)	-0.79 (-1.27, -0.31) 0.001 [-0.35 (-0.56, -0.13)]
Week 4		120 4.6 (2.69)			244 3.8 (2.59)		
Week 4 chg		120 -2.5 (2.26)	-2.44 (0.20)		244 -3.1 (2.41)	-3.15 (0.14)	-0.70 (-1.18, -0.22) 0.004 [-0.30 (-0.52, -0.08)]
Week 5		118 4.3 (2.71)			238 3.4 (2.50)		
Week 5 chg		118 -2.8 (2.32)	-2.70 (0.20)		238 -3.5 (2.40)	-3.48 (0.14)	-0.78 (-1.26, -0.30) 0.002 [-0.33 (-0.55, -0.11)]
Week 6		122 4.3 (2.76)			239 3.2 (2.50)		
Week 6 chg		122 -2.7 (2.43)	-2.70 (0.20)		239 -3.6 (2.53)	-3.61 (0.14)	-0.91 (-1.39, -0.43) <.001 [-0.36 (-0.58, -0.14)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9993
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 1.3.295.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	116	4.0 (2.76)		231	3.0 (2.47)		
Week 7 chg	116	-3.0 (2.49)	-2.97 (0.20)	231	-3.8 (2.52)	-3.81 (0.14)	-0.84 (-1.32, -0.36) <.001 [-0.34 (-0.56, -0.11)]
Week 8	116	4.0 (2.72)		227	3.0 (2.49)		
Week 8 chg	116	-3.0 (2.48)	-2.92 (0.20)	227	-3.9 (2.52)	-3.87 (0.14)	-0.95 (-1.43, -0.47) <.001 [-0.38 (-0.60, -0.15)]
Week 9	116	3.9 (2.78)		235	2.8 (2.36)		
Week 9 chg	116	-3.1 (2.48)	-3.03 (0.20)	235	-4.1 (2.49)	-4.07 (0.14)	-1.04 (-1.52, -0.56) <.001 [-0.42 (-0.64, -0.19)]
Week 10	114	3.9 (2.81)		235	2.7 (2.40)		
Week 10 chg	114	-3.1 (2.56)	-3.09 (0.20)	235	-4.1 (2.59)	-4.11 (0.14)	-1.02 (-1.50, -0.54) <.001 [-0.40 (-0.62, -0.17)]
Week 11	115	3.8 (2.71)		231	2.6 (2.33)		
Week 11 chg	115	-3.2 (2.54)	-3.10 (0.20)	231	-4.2 (2.58)	-4.22 (0.14)	-1.12 (-1.60, -0.64) <.001 [-0.44 (-0.66, -0.21)]
Week 12	115	3.8 (2.78)		234	2.7 (2.32)		
Week 12 chg	115	-3.2 (2.59)	-3.10 (0.20)	234	-4.2 (2.61)	-4.19 (0.14)	-1.09 (-1.57, -0.61) <.001 [-0.42 (-0.64, -0.19)]
Week 13	115	3.9 (2.80)		233	2.5 (2.33)		
Week 13 chg	115	-3.2 (2.52)	-3.16 (0.20)	233	-4.4 (2.66)	-4.39 (0.14)	-1.24 (-1.72, -0.75) <.001 [-0.47 (-0.70, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9993
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 1.3.295.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	116	3.8 (2.86)		223	2.5 (2.29)		
Week 14 chg	116	-3.2 (2.61)	-3.14 (0.20)	223	-4.3 (2.69)	-4.33 (0.14)	-1.20 (-1.68, -0.72) <.001 [-0.45 (-0.68, -0.22)]
Week 15	114	3.8 (2.87)		225	2.4 (2.27)		
Week 15 chg	114	-3.2 (2.56)	-3.14 (0.20)	225	-4.4 (2.64)	-4.39 (0.14)	-1.25 (-1.73, -0.77) <.001 [-0.48 (-0.71, -0.25)]
Week 16	112	3.7 (2.86)		226	2.4 (2.25)		
Week 16 chg	112	-3.3 (2.59)	-3.19 (0.20)	226	-4.4 (2.62)	-4.39 (0.14)	-1.21 (-1.69, -0.72) <.001 [-0.46 (-0.69, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9993
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 1.3.295.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	118	118 7.1 (2.21)		236	235 7.0 (2.12)			
Week 1		117 5.6 (2.41)			232 5.3 (2.35)			
Week 1 chg		117 -1.4 (1.59)	-1.41 (0.21)		232 -1.6 (1.69)	-1.59 (0.15)	-0.18 (-0.67, 0.32) [-0.11 (-0.33, 0.12)]	0.479
Week 2		118 5.1 (2.71)			229 4.5 (2.57)			
Week 2 chg		118 -2.0 (2.14)	-1.92 (0.20)		229 -2.4 (2.20)	-2.40 (0.15)	-0.48 (-0.97, 0.02) [-0.22 (-0.44, 0.00)]	0.058
Week 3		117 4.9 (2.62)			227 4.0 (2.60)			
Week 3 chg		117 -2.2 (2.10)	-2.12 (0.21)		227 -3.0 (2.34)	-2.95 (0.15)	-0.83 (-1.33, -0.34) [-0.37 (-0.59, -0.14)]	<.001
Week 4		112 4.6 (2.69)			228 3.7 (2.62)			
Week 4 chg		112 -2.5 (2.16)	-2.47 (0.21)		228 -3.2 (2.41)	-3.19 (0.15)	-0.72 (-1.22, -0.23) [-0.31 (-0.54, -0.08)]	0.004
Week 5		110 4.3 (2.73)			223 3.4 (2.53)			
Week 5 chg		110 -2.8 (2.27)	-2.72 (0.21)		223 -3.6 (2.41)	-3.53 (0.15)	-0.80 (-1.30, -0.31) [-0.34 (-0.57, -0.11)]	0.002
Week 6		114 4.3 (2.75)			223 3.2 (2.53)			
Week 6 chg		114 -2.8 (2.38)	-2.74 (0.21)		223 -3.7 (2.52)	-3.65 (0.15)	-0.91 (-1.40, -0.41) [-0.37 (-0.59, -0.14)]	<.001
Week 7		108 3.9 (2.77)			215 3.0 (2.50)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9993
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 1.3.295.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	108	108	-3.1 (2.47)	-3.00	(0.21)	215	215	-3.9 (2.49)	-3.86	(0.15)	-0.86 (-1.36, -0.36) <.001 [-0.35 (-0.58, -0.11)]
Week 8	108	108	4.0 (2.71)			211	211	2.9 (2.53)			
Week 8 chg	108	108	-3.1 (2.46)	-2.97	(0.21)	211	211	-3.9 (2.50)	-3.91	(0.15)	-0.95 (-1.45, -0.45) <.001 [-0.38 (-0.62, -0.15)]
Week 9	109	109	3.9 (2.77)			219	219	2.8 (2.39)			
Week 9 chg	109	109	-3.1 (2.44)	-3.05	(0.21)	219	219	-4.1 (2.46)	-4.14	(0.15)	-1.09 (-1.59, -0.59) <.001 [-0.44 (-0.67, -0.21)]
Week 10	107	107	3.9 (2.81)			219	219	2.7 (2.41)			
Week 10 chg	107	107	-3.1 (2.53)	-3.13	(0.21)	219	219	-4.2 (2.58)	-4.17	(0.15)	-1.04 (-1.54, -0.54) <.001 [-0.41 (-0.64, -0.17)]
Week 11	108	108	3.8 (2.69)			216	216	2.6 (2.34)			
Week 11 chg	108	108	-3.2 (2.51)	-3.14	(0.21)	216	216	-4.3 (2.56)	-4.30	(0.15)	-1.16 (-1.66, -0.66) <.001 [-0.46 (-0.69, -0.22)]
Week 12	108	108	3.8 (2.76)			218	218	2.7 (2.34)			
Week 12 chg	108	108	-3.2 (2.57)	-3.15	(0.21)	218	218	-4.2 (2.58)	-4.26	(0.15)	-1.11 (-1.60, -0.61) <.001 [-0.43 (-0.66, -0.20)]
Week 13	108	108	3.9 (2.79)			217	217	2.4 (2.34)			
Week 13 chg	108	108	-3.2 (2.49)	-3.20	(0.21)	217	217	-4.5 (2.63)	-4.46	(0.15)	-1.26 (-1.76, -0.76) <.001 [-0.49 (-0.72, -0.25)]
Week 14	109	109	3.7 (2.86)			207	207	2.5 (2.30)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9993
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.

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Table 1.3.295.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	109	-3.3 (2.60)	-3.17 (0.21)	207	-4.4 (2.66)	-4.40 (0.15)	-1.23 (-1.73, -0.73) <.001 [-0.46 (-0.70, -0.23)]
Week 15	107	3.8 (2.87)		210	2.4 (2.28)		
Week 15 chg	107	-3.2 (2.56)	-3.16 (0.21)	210	-4.5 (2.64)	-4.44 (0.15)	-1.28 (-1.78, -0.79) <.001 [-0.49 (-0.73, -0.26)]
Week 16	105	3.7 (2.87)		211	2.4 (2.27)		
Week 16 chg	105	-3.3 (2.58)	-3.22 (0.21)	211	-4.4 (2.65)	-4.42 (0.15)	-1.20 (-1.70, -0.70) <.001 [-0.46 (-0.69, -0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9993
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 1.3.295.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 7.1 (2.22)		16	16 6.2 (2.20)		
Week 1		8 5.9 (2.32)			16 5.1 (2.12)		
Week 1 chg		8 -1.2 (2.05)	-0.97 (0.86)		16 -1.1 (1.54)	-1.17 (0.60)	-0.20 (-2.39, 1.98) 0.851 [-0.12 (-0.97, 0.73)]
Week 2		8 5.2 (1.79)			16 4.7 (2.12)		
Week 2 chg		8 -1.9 (2.54)	-1.50 (0.86)		16 -1.6 (1.97)	-1.70 (0.60)	-0.19 (-2.38, 1.99) 0.857 [-0.09 (-0.94, 0.76)]
Week 3		8 4.8 (2.64)			16 4.1 (2.07)		
Week 3 chg		8 -2.3 (3.23)	-1.93 (0.86)		16 -2.1 (2.09)	-2.23 (0.60)	-0.30 (-2.49, 1.88) 0.778 [-0.12 (-0.97, 0.73)]
Week 4		8 4.7 (2.87)			16 3.9 (2.16)		
Week 4 chg		8 -2.4 (3.53)	-1.92 (0.86)		16 -2.4 (2.30)	-2.52 (0.60)	-0.60 (-2.79, 1.58) 0.575 [-0.22 (-1.07, 0.63)]
Week 5		8 4.4 (2.72)			15 3.4 (2.10)		
Week 5 chg		8 -2.7 (3.11)	-2.29 (0.86)		15 -2.6 (2.13)	-2.92 (0.60)	-0.63 (-2.82, 1.57) 0.563 [-0.25 (-1.11, 0.61)]
Week 6		8 4.6 (2.94)			16 3.3 (2.14)		
Week 6 chg		8 -2.5 (3.13)	-2.03 (0.86)		16 -2.9 (2.64)	-3.07 (0.60)	-1.03 (-3.22, 1.16) 0.341 [-0.37 (-1.22, 0.49)]
Week 7		8 4.2 (2.70)			16 3.3 (2.04)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9993
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 1.3.295.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	8	-2.9 (2.97)	-2.37 (0.86)	16	-3.0 (2.74)	-3.14 (0.60)	-0.77 (-2.96, 1.41) 0.472 [-0.28 (-1.13, 0.58)]
Week 8	8	4.5 (2.98)		16	3.2 (2.10)		
Week 8 chg	8	-2.6 (2.87)	-2.15 (0.86)	16	-3.1 (2.71)	-3.21 (0.60)	-1.07 (-3.25, 1.12) 0.325 [-0.39 (-1.24, 0.47)]
Week 9	7	4.1 (3.14)		16	3.4 (1.88)		
Week 9 chg	7	-2.6 (3.14)	-2.52 (0.87)	16	-2.9 (2.59)	-3.05 (0.60)	-0.53 (-2.73, 1.66) 0.621 [-0.19 (-1.08, 0.70)]
Week 10	7	4.2 (3.11)		16	3.0 (2.21)		
Week 10 chg	7	-2.5 (3.06)	-2.48 (0.87)	16	-3.2 (2.77)	-3.36 (0.60)	-0.89 (-3.08, 1.31) 0.414 [-0.31 (-1.20, 0.58)]
Week 11	7	4.1 (3.19)		15	3.4 (2.04)		
Week 11 chg	7	-2.5 (3.10)	-2.51 (0.87)	15	-2.6 (2.35)	-3.17 (0.60)	-0.66 (-2.86, 1.54) 0.541 [-0.26 (-1.16, 0.65)]
Week 12	7	4.3 (3.27)		16	3.1 (2.14)		
Week 12 chg	7	-2.4 (3.02)	-2.35 (0.87)	16	-3.2 (2.83)	-3.33 (0.60)	-0.98 (-3.17, 1.22) 0.369 [-0.34 (-1.23, 0.56)]
Week 13	7	4.2 (3.20)		16	3.0 (2.07)		
Week 13 chg	7	-2.4 (2.94)	-2.41 (0.87)	16	-3.2 (2.85)	-3.40 (0.60)	-0.99 (-3.19, 1.20) 0.361 [-0.35 (-1.24, 0.55)]
Week 14	7	4.1 (3.07)		16	3.0 (2.11)		

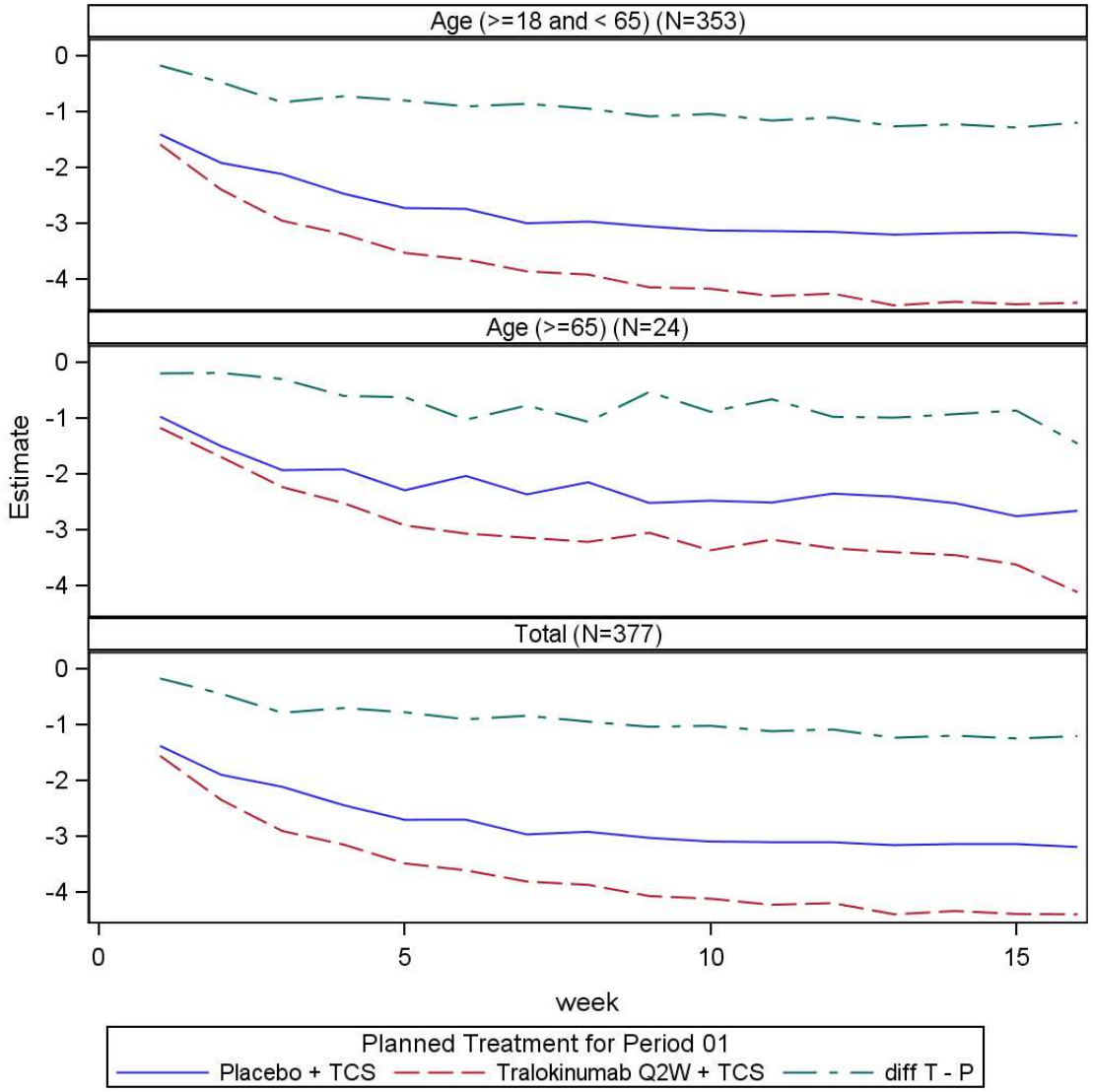
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9993
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.3.295.3.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	7	-2.6 (2.83)	-2.52 (0.87)	16	-3.3 (2.93)	-3.45 (0.60)	-0.93 (-3.12, 1.27) [-0.32 (-1.21, 0.57)]	0.392
Week 15	7	3.9 (3.01)		15	2.9 (2.15)			
Week 15 chg	7	-2.8 (2.84)	-2.75 (0.87)	15	-3.6 (2.53)	-3.62 (0.60)	-0.86 (-3.06, 1.33) [-0.33 (-1.23, 0.57)]	0.426
Week 16	7	4.0 (2.92)		15	2.4 (1.99)			
Week 16 chg	7	-2.7 (2.84)	-2.66 (0.87)	15	-4.1 (2.32)	-4.11 (0.60)	-1.45 (-3.65, 0.74) [-0.59 (-1.50, 0.33)]	0.185

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9993
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 1.3.295.3.2: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, 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 1.3.297.3.1: Total, Age group, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)		
Week 2		124 51.4 (17.14)			250 46.5 (16.69)		
Week 2 chg		124 -17.3 (16.94)	-16.83 (1.52)		250 -20.5 (14.91)	-20.64 (1.07)	-3.81 (-7.47, -0.15) 0.042 [-0.24 (-0.46, -0.03)]
Week 4		126 46.6 (20.16)			246 40.1 (16.71)		
Week 4 chg		126 -22.3 (19.12)	-21.68 (1.52)		246 -26.9 (15.62)	-26.91 (1.08)	-5.23 (-8.89, -1.57) 0.005 [-0.31 (-0.53, -0.09)]
Week 6		125 43.6 (20.47)			247 35.7 (16.22)		
Week 6 chg		125 -25.2 (18.79)	-24.72 (1.52)		247 -31.2 (15.78)	-31.15 (1.08)	-6.43 (-10.1, -2.76) <.001 [-0.38 (-0.60, -0.16)]
Week 8		122 41.9 (19.17)			243 32.7 (16.17)		
Week 8 chg		122 -26.8 (17.76)	-25.99 (1.53)		243 -34.2 (16.42)	-34.13 (1.08)	-8.15 (-11.8, -4.47) <.001 [-0.48 (-0.70, -0.26)]
Week 10		118 40.4 (20.53)			236 30.2 (16.85)		
Week 10 chg		118 -28.0 (19.22)	-27.39 (1.54)		236 -36.5 (18.20)	-36.38 (1.09)	-8.99 (-12.7, -5.29) <.001 [-0.48 (-0.71, -0.26)]
Week 12		119 39.6 (21.65)			238 29.4 (17.23)		
Week 12 chg		119 -28.8 (20.95)	-28.05 (1.53)		238 -37.6 (18.51)	-37.68 (1.08)	-9.63 (-13.3, -5.94) <.001 [-0.50 (-0.72, -0.27)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9839
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.

12MAY21 13:11 LP0162-Payer /p_mmrm3/t_t_agr2_e97_39_w16.txt

Table 1.3.297.3.1: Total, Age group, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		118 38.8 (22.39)			235 28.5 (18.20)		
Week 14 chg		118 -29.6 (21.97)	-28.76 (1.54)		235 -38.4 (18.95)	-38.28 (1.09)	-9.52 (-13.2, -5.82) <.001 [-0.48 (-0.70, -0.25)]
Week 16		122 40.9 (23.52)			241 29.4 (18.62)		
Week 16 chg		122 -27.7 (22.50)	-26.84 (1.53)		241 -37.4 (19.31)	-37.43 (1.08)	-10.59 (-14.3, -6.91) <.001 [-0.52 (-0.74, -0.30)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9839
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.

12MAY21 13:11 LP0162-Payer /p_mmrm3/t_t_agr2_e97_39_w16.txt

Table 1.3.297.3.1: Total, Age group, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	118	118 68.7 (13.39)		236	236 67.3 (13.18)		
Week 2		116 51.4 (17.03)			234 46.7 (16.68)		
Week 2 chg		116 -17.1 (16.96)	-16.83 (1.57)		234 -20.6 (15.07)	-20.73 (1.11)	-3.90 (-7.67, -0.12) 0.043 [-0.25 (-0.47, -0.02)]
Week 4		118 46.7 (20.05)			230 40.1 (16.86)		
Week 4 chg		118 -22.1 (18.98)	-21.60 (1.57)		230 -27.2 (15.87)	-27.16 (1.11)	-5.56 (-9.33, -1.79) 0.004 [-0.33 (-0.55, -0.10)]
Week 6		117 43.5 (20.12)			231 35.7 (16.33)		
Week 6 chg		117 -25.1 (18.45)	-24.84 (1.57)		231 -31.6 (15.80)	-31.48 (1.11)	-6.63 (-10.4, -2.86) <.001 [-0.40 (-0.62, -0.17)]
Week 8		114 41.8 (18.73)			227 32.8 (16.32)		
Week 8 chg		114 -26.8 (17.40)	-26.06 (1.58)		227 -34.4 (16.27)	-34.21 (1.11)	-8.15 (-11.9, -4.36) <.001 [-0.49 (-0.72, -0.26)]
Week 10		111 40.4 (20.45)			220 30.1 (17.16)		
Week 10 chg		111 -27.9 (19.17)	-27.27 (1.58)		220 -37.0 (17.94)	-36.71 (1.12)	-9.44 (-13.3, -5.63) <.001 [-0.51 (-0.75, -0.28)]
Week 12		112 39.7 (21.57)			222 29.5 (17.21)		
Week 12 chg		112 -28.6 (20.89)	-27.91 (1.58)		222 -37.8 (17.96)	-37.80 (1.12)	-9.89 (-13.7, -6.09) <.001 [-0.52 (-0.75, -0.29)]
Week 14		111 38.6 (22.11)			219 28.6 (18.32)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9839
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 1.3.297.3.1: Total, Age group, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	111	-29.7 (21.79)	-28.87 (1.58)	219	-38.6 (18.87)	-38.38 (1.12)	-9.51 (-13.3, -5.70) [-0.48 (-0.71, -0.25)]	<.001
Week 16	115	40.7 (23.42)		226	29.5 (18.77)			
Week 16 chg	115	-27.8 (22.45)	-26.98 (1.57)	226	-37.5 (19.18)	-37.50 (1.12)	-10.52 (-14.3, -6.73) [-0.52 (-0.75, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9839
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 1.3.297.3.1: Total, Age group, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 70.9 (10.13)		16	16 62.1 (13.87)		
Week 2		8 51.6 (19.92)			16 43.8 (17.16)		
Week 2 chg		8 -19.3 (17.65)	-17.71 (6.84)		16 -18.3 (12.62)	-18.98 (4.72)	-1.27 (-18.7, 16.17) 0.883 [-0.09 (-0.94, 0.76)]
Week 4		8 45.5 (23.20)			16 40.0 (14.78)		
Week 4 chg		8 -25.4 (22.34)	-23.21 (6.84)		16 -22.1 (10.59)	-23.09 (4.72)	0.12 (-17.3, 17.55) 0.989 [0.01 (-0.84, 0.86)]
Week 6		8 45.3 (26.64)			16 37.0 (14.93)		
Week 6 chg		8 -25.6 (24.69)	-22.61 (6.84)		16 -25.1 (14.61)	-26.52 (4.72)	-3.91 (-21.3, 13.52) 0.650 [-0.21 (-1.06, 0.64)]
Week 8		8 42.9 (26.21)			16 30.6 (14.15)		
Week 8 chg		8 -28.0 (23.69)	-23.07 (6.84)		16 -31.5 (18.86)	-33.78 (4.72)	-10.72 (-28.1, 6.71) 0.219 [-0.52 (-1.38, 0.34)]
Week 10		7 39.2 (23.44)			16 32.1 (12.02)		
Week 10 chg		7 -31.1 (21.35)	-26.46 (6.96)		16 -30.0 (21.02)	-33.23 (4.72)	-6.77 (-24.4, 10.81) 0.438 [-0.32 (-1.21, 0.57)]
Week 12		7 38.0 (24.59)			16 28.0 (18.09)		
Week 12 chg		7 -32.3 (23.34)	-27.23 (6.96)		16 -34.2 (25.44)	-37.63 (4.72)	-10.40 (-28.0, 7.18) 0.237 [-0.42 (-1.31, 0.48)]
Week 14		7 41.8 (28.25)			16 26.9 (16.88)		

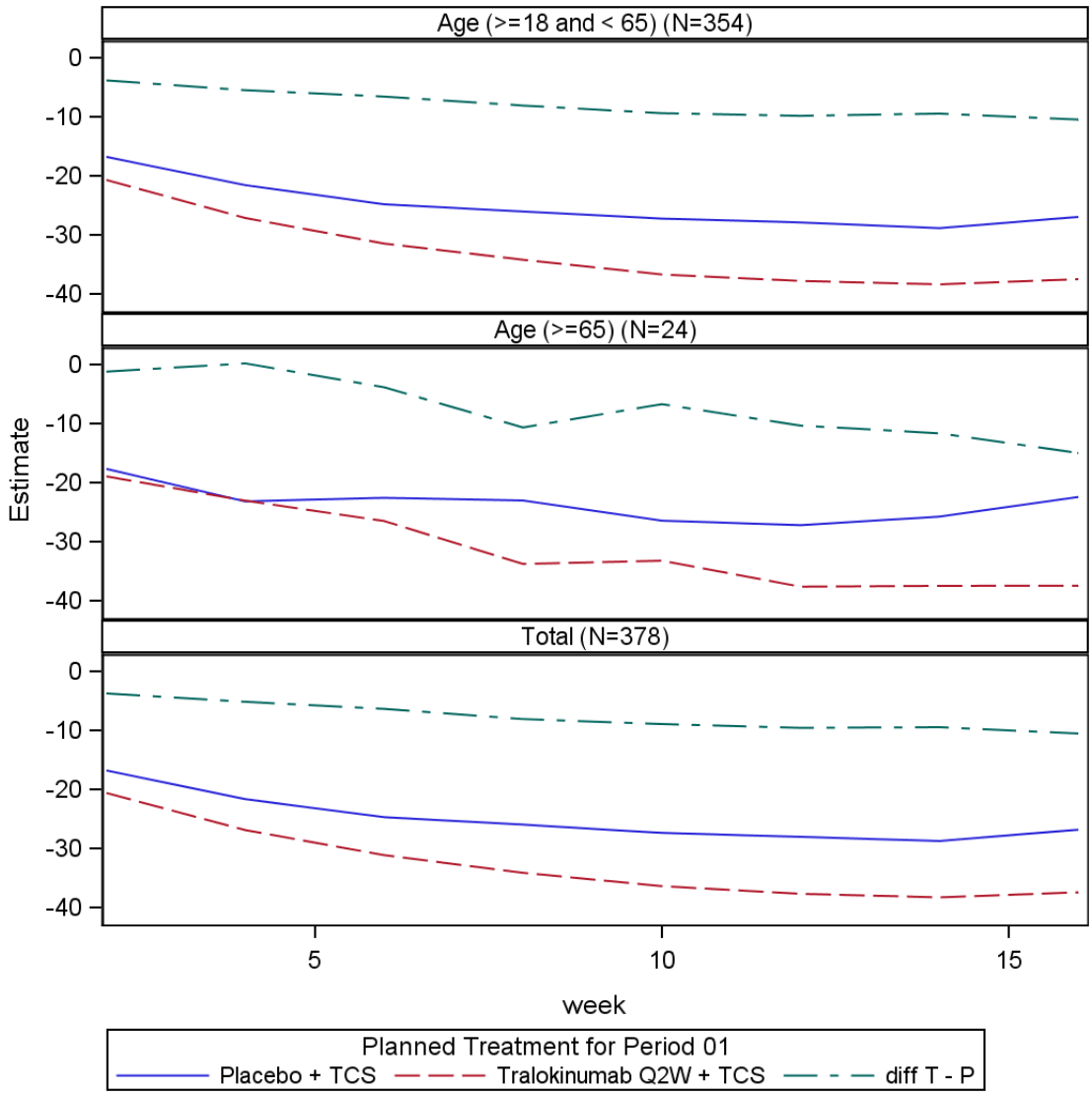
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9839
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.3.297.3.1: Total, Age group, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg		7 -28.5 (26.57)	-25.78 (6.96)		16 -35.2 (20.44)	-37.48 (4.72)	-11.70 (-29.3, 5.88) [-0.52 (-1.42, 0.38)]	0.185
Week 16		7 44.2 (26.82)			15 27.0 (16.47)			
Week 16 chg		7 -26.1 (25.11)	-22.46 (6.96)		15 -35.6 (21.94)	-37.48 (4.75)	-15.02 (-32.6, 2.59) [-0.65 (-1.57, 0.26)]	0.092

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9839
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 1.3.297.3.2: Total, Age group, change in SCORAD, Treatment policy estimand, LP0162-1339, 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 1.3.299.3.1: Total, Age group, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score								
Total								
Baseline	126	125 17.2 (7.15)		252	250 17.6 (7.07)			
Week 2		121 9.8 (7.21)			249 8.6 (6.22)			
Week 2 chg		121 -7.3 (6.72)	-7.51 (0.53)		249 -9.0 (7.25)	-8.97 (0.37)	-1.46 (-2.73, -0.19)	0.024
							[-0.21 (-0.42, 0.01)]	
Week 4		122 9.1 (7.39)			245 7.4 (6.28)			
Week 4 chg		122 -8.1 (7.14)	-8.21 (0.53)		245 -10.2 (7.54)	-10.08 (0.37)	-1.87 (-3.14, -0.60)	0.004
							[-0.25 (-0.47, -0.03)]	
Week 6		123 8.4 (6.88)			242 6.3 (5.75)			
Week 6 chg		123 -8.8 (6.70)	-9.03 (0.53)		242 -11.3 (7.41)	-11.01 (0.37)	-1.99 (-3.25, -0.72)	0.002
							[-0.28 (-0.49, -0.06)]	
Week 8		120 8.1 (6.80)			239 6.2 (5.71)			
Week 8 chg		120 -9.1 (7.09)	-9.21 (0.53)		239 -11.6 (7.90)	-11.35 (0.37)	-2.14 (-3.41, -0.87)	0.001
							[-0.28 (-0.50, -0.06)]	
Week 12		116 7.9 (7.06)			227 5.7 (5.50)			
Week 12 chg		116 -9.0 (7.22)	-9.18 (0.53)		227 -11.9 (7.98)	-11.80 (0.38)	-2.62 (-3.90, -1.34)	<.001
							[-0.34 (-0.56, -0.11)]	
Week 16		119 8.4 (7.30)			237 5.7 (6.02)			
Week 16 chg		119 -8.8 (7.09)	-9.07 (0.53)		237 -11.8 (7.57)	-11.70 (0.38)	-2.64 (-3.91, -1.36)	<.001
							[-0.36 (-0.58, -0.13)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8723
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 1.3.299.3.1: Total, Age group, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)												
Baseline	118	117	17.3 (7.03)			236	234	17.9 (7.01)				
Week 2		113	10.1 (7.27)				233	8.7 (6.37)				
Week 2 chg		113	-7.1 (6.48)	-7.42	(0.55)		233	-9.2 (7.24)	-9.13	(0.39)	-1.71 (-3.04, -0.38) [-0.24 (-0.47, -0.02)]	0.012
Week 4		115	9.3 (7.43)				229	7.5 (6.43)				
Week 4 chg		115	-8.0 (7.06)	-8.20	(0.55)		229	-10.5 (7.53)	-10.28	(0.39)	-2.07 (-3.40, -0.74) [-0.28 (-0.51, -0.06)]	0.002
Week 6		115	8.6 (6.97)				226	6.5 (5.88)				
Week 6 chg		115	-8.6 (6.62)	-9.00	(0.55)		226	-11.5 (7.41)	-11.19	(0.39)	-2.19 (-3.52, -0.86) [-0.31 (-0.53, -0.08)]	0.001
Week 8		113	8.3 (6.87)				223	6.2 (5.84)				
Week 8 chg		113	-9.0 (7.13)	-9.26	(0.55)		223	-11.9 (7.87)	-11.57	(0.39)	-2.30 (-3.64, -0.97) [-0.30 (-0.53, -0.07)]	<.001
Week 12		109	8.1 (7.15)				212	5.6 (5.57)				
Week 12 chg		109	-9.0 (7.32)	-9.22	(0.56)		212	-12.3 (7.89)	-12.11	(0.40)	-2.89 (-4.24, -1.55) [-0.38 (-0.61, -0.14)]	<.001
Week 16		112	8.6 (7.39)				222	5.9 (6.11)				
Week 16 chg		112	-8.7 (7.15)	-9.07	(0.55)		222	-12.1 (7.62)	-11.86	(0.39)	-2.80 (-4.14, -1.46) [-0.37 (-0.60, -0.15)]	<.001

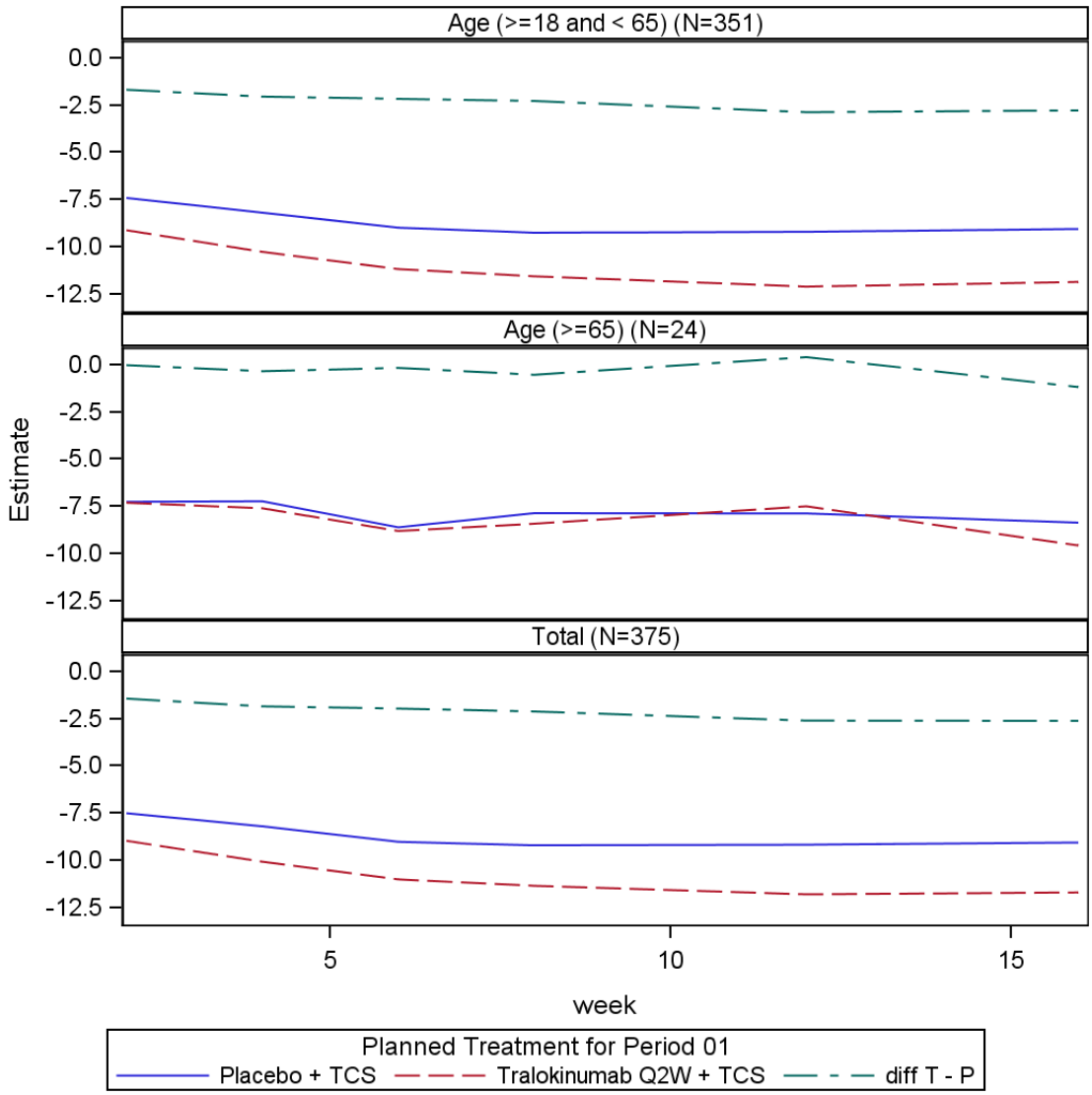
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8723
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.3.299.3.1: Total, Age group, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=65)								
Baseline	8	8 16.1 (9.26)		16	16 12.3 (5.88)			
Week 2		8 5.9 (5.06)			16 6.2 (2.64)			
Week 2 chg		8 -10.3 (9.53)	-7.28 (1.47)		16 -6.1 (7.03)	-7.32 (1.01)	-0.05 (-3.70, 3.60) [-0.01 (-0.85, 0.84)]	0.978
Week 4		7 6.7 (6.68)			16 5.8 (3.30)			
Week 4 chg		7 -9.1 (8.90)	-7.24 (1.53)		16 -6.6 (6.94)	-7.61 (1.01)	-0.37 (-4.11, 3.37) [-0.05 (-0.94, 0.84)]	0.843
Week 6		8 4.9 (4.36)			16 4.6 (3.05)			
Week 6 chg		8 -11.3 (7.70)	-8.62 (1.47)		16 -7.8 (6.68)	-8.81 (1.01)	-0.19 (-3.84, 3.45) [-0.03 (-0.88, 0.82)]	0.915
Week 8		7 5.7 (5.28)			16 4.9 (3.17)			
Week 8 chg		7 -11.3 (6.52)	-7.87 (1.55)		16 -7.4 (7.37)	-8.43 (1.01)	-0.56 (-4.34, 3.22) [-0.08 (-0.97, 0.81)]	0.769
Week 12		7 5.7 (5.28)			15 5.9 (4.56)			
Week 12 chg		7 -8.7 (5.74)	-7.89 (1.51)		15 -6.3 (7.54)	-7.51 (1.04)	0.38 (-3.34, 4.09) [0.05 (-0.84, 0.95)]	0.840
Week 16		7 5.3 (4.89)			15 3.7 (4.04)			
Week 16 chg		7 -9.1 (6.52)	-8.37 (1.51)		15 -8.7 (6.29)	-9.58 (1.04)	-1.20 (-4.91, 2.50) [-0.19 (-1.09, 0.71)]	0.518

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8723
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 1.3.299.3.2: Total, Age group, change in DLQI, Treatment policy estimand, LP0162-1339, 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 1.3.300.3.1: Total, Age group, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total											
Total											
Baseline	126	124	22.4 (5.63)			252	250	22.3 (5.09)			
Week 2		120	16.2 (7.55)				248	14.4 (6.85)			
Week 2 chg		120	-6.1 (6.67)	-6.14	(0.61)		248	-7.8 (6.57)	-7.88	(0.42)	-1.74 (-3.19, -0.29) 0.019 [-0.26 (-0.48, -0.04)]
Week 4		121	15.5 (7.82)				244	12.5 (6.95)			
Week 4 chg		121	-6.8 (7.00)	-6.89	(0.60)		244	-9.8 (7.02)	-9.82	(0.43)	-2.94 (-4.39, -1.48) <.001 [-0.42 (-0.64, -0.20)]
Week 6		122	14.7 (7.89)				242	11.4 (6.75)			
Week 6 chg		122	-7.7 (7.44)	-7.68	(0.60)		242	-10.9 (6.87)	-10.80	(0.43)	-3.12 (-4.57, -1.66) <.001 [-0.44 (-0.66, -0.22)]
Week 8		119	14.6 (7.88)				239	11.2 (7.08)			
Week 8 chg		119	-7.7 (7.38)	-7.60	(0.61)		239	-11.1 (7.24)	-11.05	(0.43)	-3.45 (-4.91, -1.99) <.001 [-0.47 (-0.70, -0.25)]
Week 12		115	14.0 (8.12)				227	10.6 (6.62)			
Week 12 chg		115	-8.2 (7.71)	-7.99	(0.61)		227	-11.6 (6.72)	-11.65	(0.43)	-3.67 (-5.14, -2.20) <.001 [-0.52 (-0.75, -0.29)]
Week 16		118	14.7 (8.27)				237	10.5 (7.20)			
Week 16 chg		118	-7.8 (7.40)	-7.85	(0.61)		237	-11.7 (7.37)	-11.68	(0.43)	-3.83 (-5.28, -2.37) <.001 [-0.52 (-0.74, -0.29)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9645
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 1.3.300.3.1: Total, Age group, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	118	116 22.4 (5.67)		236	234 22.6 (4.73)			
Week 2		112 16.2 (7.68)			232 14.6 (6.86)			
Week 2 chg		112 -6.1 (6.68)	-6.27 (0.64)		232 -8.0 (6.55)	-7.99 (0.45)	-1.72 (-3.25, -0.20) [-0.26 (-0.49, -0.04)]	0.027
Week 4		114 15.5 (7.90)			229 12.7 (7.00)			
Week 4 chg		114 -6.8 (7.12)	-6.90 (0.63)		229 -10.0 (7.11)	-9.91 (0.45)	-3.02 (-4.54, -1.49) [-0.42 (-0.65, -0.20)]	<.001
Week 6		114 14.6 (8.09)			226 11.5 (6.82)			
Week 6 chg		114 -7.8 (7.50)	-7.85 (0.63)		226 -11.1 (6.90)	-10.94 (0.45)	-3.09 (-4.62, -1.57) [-0.44 (-0.66, -0.21)]	<.001
Week 8		112 14.7 (8.00)			223 11.4 (7.17)			
Week 8 chg		112 -7.6 (7.34)	-7.68 (0.64)		223 -11.3 (7.31)	-11.18 (0.45)	-3.50 (-5.03, -1.97) [-0.48 (-0.71, -0.25)]	<.001
Week 12		108 14.1 (8.24)			212 10.7 (6.66)			
Week 12 chg		108 -8.1 (7.70)	-8.05 (0.64)		212 -11.8 (6.74)	-11.76 (0.45)	-3.71 (-5.25, -2.17) [-0.52 (-0.76, -0.29)]	<.001
Week 16		111 14.8 (8.43)			222 10.7 (7.25)			
Week 16 chg		111 -7.7 (7.48)	-7.83 (0.64)		222 -11.8 (7.44)	-11.73 (0.45)	-3.90 (-5.43, -2.36) [-0.52 (-0.75, -0.29)]	<.001

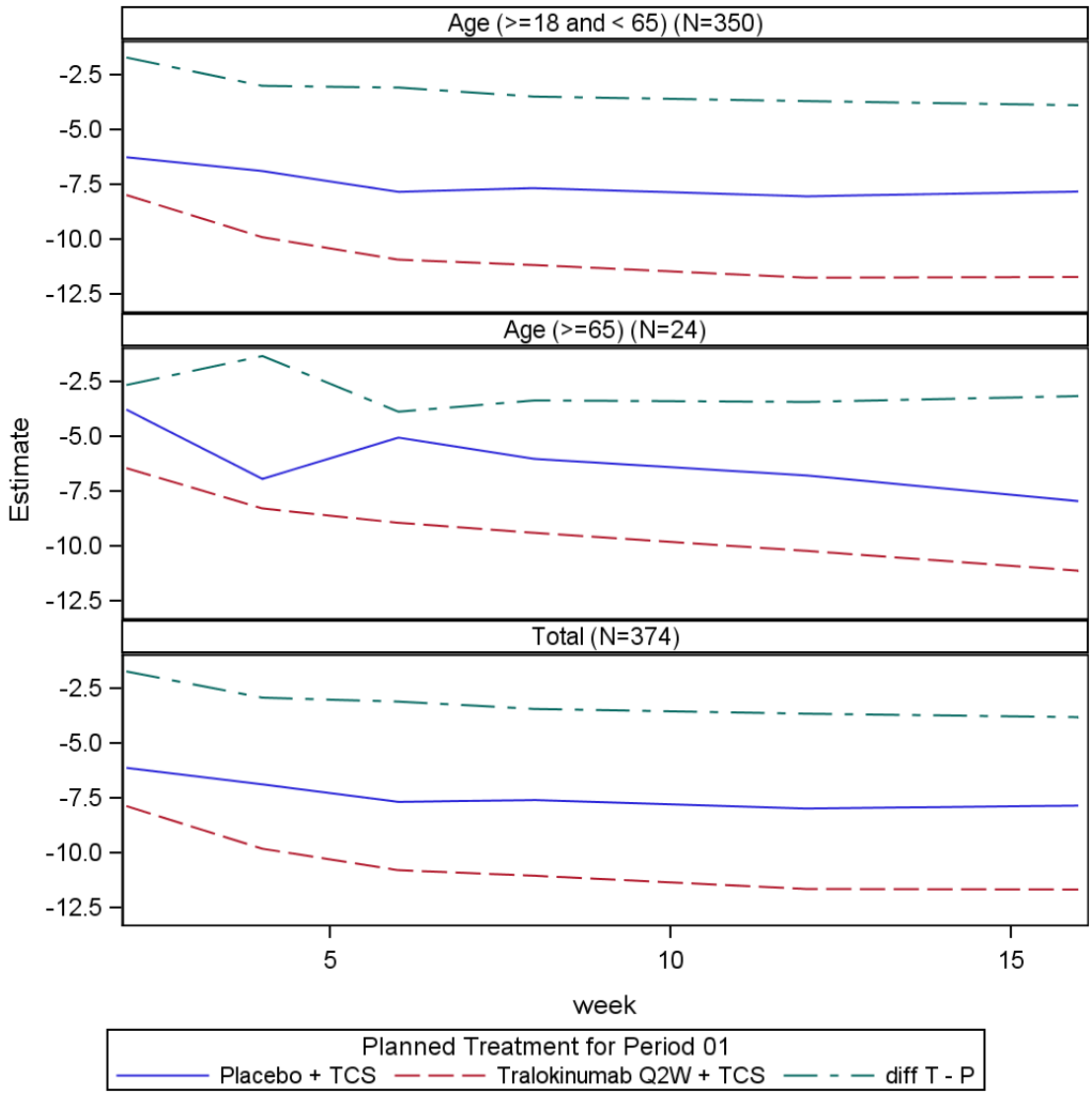
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9645
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.3.300.3.1: Total, Age group, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 21.3 (5.12)		16	16 17.4 (7.47)		
Week 2		8 16.1 (5.84)			16 11.6 (6.23)		
Week 2 chg		8 -5.1 (6.81)	-3.79 (1.87)		16 -5.8 (6.80)	-6.46 (1.30)	-2.67 (-7.39, 2.05) 0.260 [-0.39 (-1.25, 0.46)]
Week 4		7 14.1 (6.82)			15 9.3 (5.38)		
Week 4 chg		7 -7.0 (5.16)	-6.95 (1.93)		15 -7.7 (5.28)	-8.29 (1.33)	-1.35 (-6.19, 3.49) 0.577 [-0.26 (-1.16, 0.64)]
Week 6		8 14.8 (4.40)			16 9.2 (5.47)		
Week 6 chg		8 -6.5 (6.91)	-5.06 (1.87)		16 -8.2 (5.94)	-8.95 (1.30)	-3.88 (-8.61, 0.84) 0.104 [-0.62 (-1.49, 0.25)]
Week 8		7 13.1 (6.04)			16 8.8 (5.32)		
Week 8 chg		7 -9.1 (8.51)	-6.03 (1.96)		16 -8.6 (5.76)	-9.41 (1.30)	-3.37 (-8.23, 1.49) 0.169 [-0.51 (-1.41, 0.39)]
Week 12		7 13.4 (6.40)			15 8.2 (5.71)		
Week 12 chg		7 -8.9 (8.47)	-6.79 (1.95)		15 -9.2 (5.99)	-10.23 (1.32)	-3.44 (-8.31, 1.43) 0.162 [-0.50 (-1.41, 0.41)]
Week 16		7 12.3 (4.82)			15 6.5 (5.26)		
Week 16 chg		7 -10.0 (5.94)	-7.96 (1.95)		15 -10.5 (6.38)	-11.13 (1.33)	-3.17 (-8.06, 1.71) 0.198 [-0.51 (-1.42, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9645
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 1.3.300.3.2: Total, Age group, change in POEM, Treatment policy estimand, LP0162-1339, 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 1.3.318.3.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss										
Total										
Baseline	126	126	6.9 (2.72)		252	252	6.5 (2.77)			
Week 2		124	4.4 (3.05)			250	3.7 (2.95)			
Week 2 chg		124	-2.5 (2.93)	-2.39 (0.24)		250	-2.8 (2.95)	-2.85 (0.17)	-0.46 (-1.03, 0.11) [-0.16 (-0.37, 0.06)]	0.115
Week 4		126	3.7 (3.07)			246	3.1 (2.84)			
Week 4 chg		126	-3.1 (3.14)	-2.96 (0.24)		246	-3.3 (3.01)	-3.36 (0.17)	-0.40 (-0.97, 0.17) [-0.13 (-0.35, 0.08)]	0.167
Week 6		125	3.4 (2.99)			247	2.7 (2.75)			
Week 6 chg		125	-3.5 (3.05)	-3.31 (0.24)		247	-3.7 (3.04)	-3.71 (0.17)	-0.40 (-0.97, 0.17) [-0.13 (-0.35, 0.08)]	0.166
Week 8		122	3.4 (3.15)			243	2.5 (2.71)			
Week 8 chg		122	-3.4 (3.28)	-3.26 (0.24)		243	-3.9 (2.98)	-3.97 (0.17)	-0.71 (-1.28, -0.14) [-0.23 (-0.45, -0.01)]	0.015
Week 10		118	3.2 (2.97)			236	2.3 (2.60)			
Week 10 chg		118	-3.6 (3.11)	-3.48 (0.24)		236	-4.1 (3.15)	-4.17 (0.17)	-0.70 (-1.27, -0.12) [-0.22 (-0.44, -0.00)]	0.017
Week 12		119	3.1 (3.11)			238	2.2 (2.57)			
Week 12 chg		119	-3.7 (3.14)	-3.54 (0.24)		238	-4.2 (3.15)	-4.25 (0.17)	-0.71 (-1.29, -0.14) [-0.23 (-0.45, -0.01)]	0.015

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9807
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 VAS = Treatment*Week + [Baseline VAS]*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 1.3.318.3.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	3.0 (3.03)		235	2.0 (2.52)			
Week 14 chg	118	-3.8 (3.10)	-3.60 (0.24)	235	-4.4 (3.19)	-4.42 (0.17)	-0.82 (-1.39, -0.24) [-0.26 (-0.48, -0.04)]	0.005
Week 16	122	3.2 (3.24)		241	2.2 (2.68)			
Week 16 chg	122	-3.7 (3.20)	-3.46 (0.24)	241	-4.2 (3.34)	-4.27 (0.17)	-0.80 (-1.38, -0.23) [-0.24 (-0.46, -0.03)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9807
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 VAS = Treatment*Week + [Baseline VAS]*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 1.3.318.3.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)										
Baseline	118	118	6.9 (2.75)		236	236	6.5 (2.77)			
Week 2		116	4.4 (3.04)			234	3.7 (3.00)			
Week 2 chg		116	-2.4 (2.84)	-2.37 (0.25)		234	-2.8 (2.99)	-2.85 (0.17)	-0.48 (-1.07, 0.11) [-0.16 (-0.39, 0.06)]	0.112
Week 4		118	3.7 (3.08)			230	3.1 (2.89)			
Week 4 chg		118	-3.1 (3.10)	-2.97 (0.25)		230	-3.4 (3.07)	-3.38 (0.17)	-0.41 (-1.01, 0.18) [-0.13 (-0.36, 0.09)]	0.171
Week 6		117	3.4 (2.98)			231	2.8 (2.79)			
Week 6 chg		117	-3.5 (3.00)	-3.37 (0.25)		231	-3.7 (3.06)	-3.73 (0.17)	-0.36 (-0.95, 0.23) [-0.12 (-0.34, 0.10)]	0.235
Week 8		114	3.4 (3.15)			227	2.5 (2.76)			
Week 8 chg		114	-3.4 (3.27)	-3.31 (0.25)		227	-4.0 (3.03)	-3.98 (0.17)	-0.68 (-1.27, -0.08) [-0.22 (-0.44, 0.01)]	0.026
Week 10		111	3.2 (2.97)			220	2.3 (2.64)			
Week 10 chg		111	-3.7 (3.08)	-3.53 (0.25)		220	-4.2 (3.16)	-4.21 (0.18)	-0.68 (-1.28, -0.08) [-0.22 (-0.45, 0.01)]	0.026
Week 12		112	3.1 (3.10)			222	2.2 (2.62)			
Week 12 chg		112	-3.7 (3.14)	-3.60 (0.25)		222	-4.2 (3.16)	-4.26 (0.18)	-0.66 (-1.26, -0.06) [-0.21 (-0.44, 0.02)]	0.031
Week 14		111	3.0 (3.02)			219	2.0 (2.57)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9807
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 VAS = Treatment*Week + [Baseline VAS]*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 1.3.318.3.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	111	-3.8 (3.10)	-3.64 (0.25)	219	-4.4 (3.21)	-4.42 (0.18)	-0.78 (-1.37, -0.18) [-0.24 (-0.47, -0.02)]	0.011
Week 16	115	3.1 (3.24)		226	2.2 (2.70)			
Week 16 chg	115	-3.7 (3.21)	-3.49 (0.25)	226	-4.2 (3.40)	-4.28 (0.18)	-0.79 (-1.38, -0.19) [-0.24 (-0.46, -0.01)]	0.010

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9807
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 VAS = Treatment*Week + [Baseline VAS]*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 1.3.318.3.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 7.5 (2.39)		16	16 5.5 (2.65)		
Week 2		8 4.0 (3.31)			16 2.9 (2.19)		
Week 2 chg		8 -3.5 (4.19)	-2.52 (0.93)		16 -2.6 (2.18)	-3.01 (0.64)	-0.49 (-2.89, 1.90) 0.677 [-0.17 (-1.02, 0.68)]
Week 4		8 3.9 (3.18)			16 2.8 (2.01)		
Week 4 chg		8 -3.6 (3.98)	-2.71 (0.93)		16 -2.7 (1.97)	-3.13 (0.64)	-0.43 (-2.82, 1.97) 0.719 [-0.15 (-1.00, 0.70)]
Week 6		8 4.2 (3.26)			16 2.3 (2.13)		
Week 6 chg		8 -3.3 (3.93)	-2.23 (0.93)		16 -3.1 (2.65)	-3.63 (0.64)	-1.40 (-3.80, 0.99) 0.240 [-0.45 (-1.31, 0.41)]
Week 8		8 4.1 (3.30)			16 2.1 (2.01)		
Week 8 chg		8 -3.3 (3.61)	-2.49 (0.93)		16 -3.4 (2.18)	-3.75 (0.64)	-1.26 (-3.65, 1.13) 0.290 [-0.46 (-1.32, 0.39)]
Week 10		7 4.2 (3.10)			16 2.2 (2.10)		
Week 10 chg		7 -3.0 (3.68)	-2.39 (0.95)		16 -3.3 (2.95)	-3.83 (0.64)	-1.44 (-3.84, 0.97) 0.233 [-0.45 (-1.35, 0.45)]
Week 12		7 4.2 (3.37)			16 1.7 (1.70)		
Week 12 chg		7 -3.1 (3.41)	-2.42 (0.95)		16 -3.8 (3.02)	-4.35 (0.64)	-1.93 (-4.34, 0.48) 0.112 [-0.62 (-1.52, 0.29)]
Week 14		7 3.8 (3.39)			16 1.5 (1.80)		

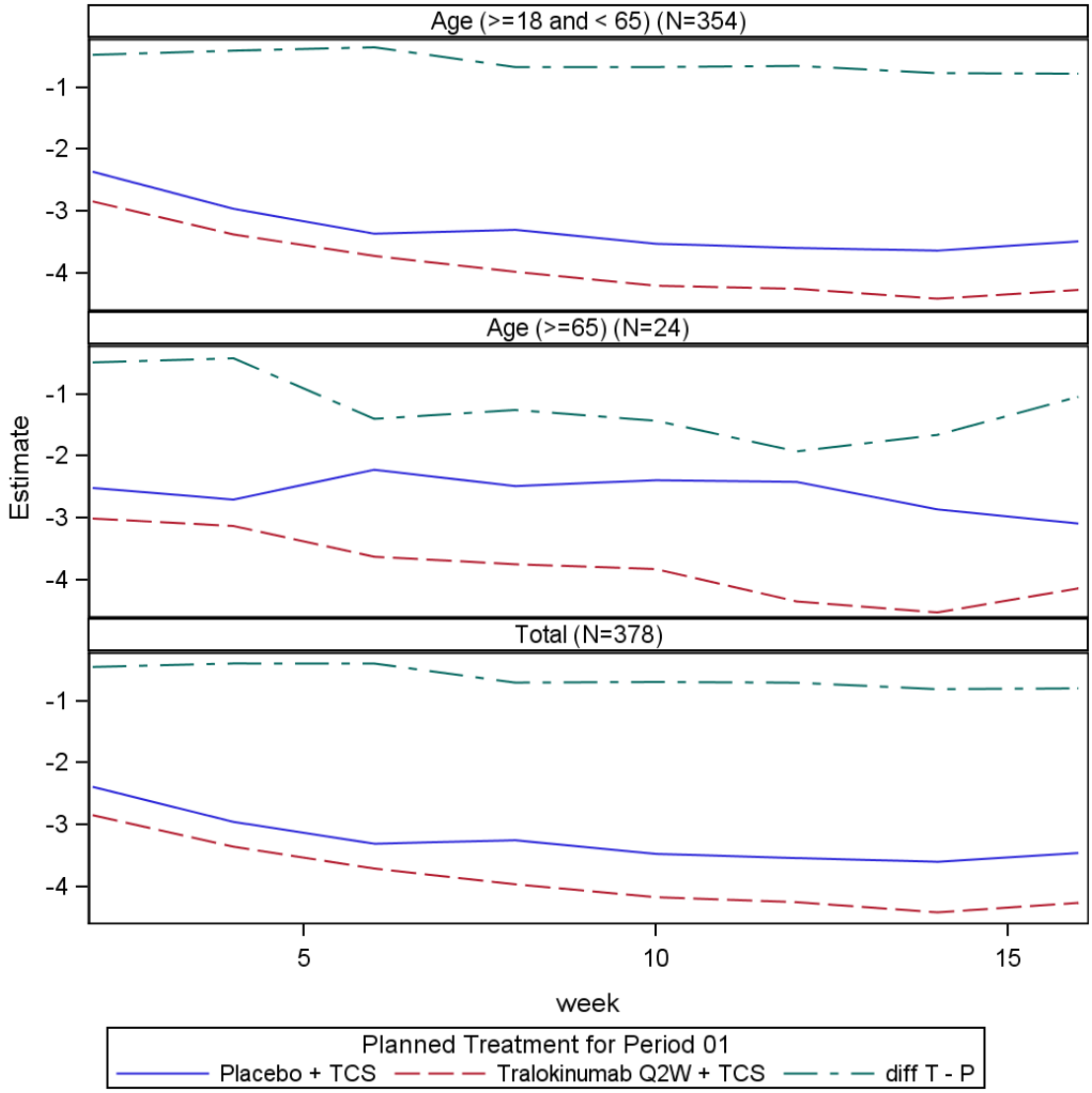
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9807
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*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 1.3.318.3.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	7	-3.4 (3.34)	-2.87 (0.95)	16	-4.0 (2.83)	-4.53 (0.64)	-1.66 (-4.07, 0.75) [-0.56 (-1.46, 0.35)]	0.169
Week 16	7	3.9 (3.38)		15	1.8 (2.34)			
Week 16 chg	7	-3.3 (3.32)	-3.09 (0.95)	15	-3.9 (2.29)	-4.14 (0.64)	-1.05 (-3.46, 1.36) [-0.40 (-1.30, 0.51)]	0.382

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9807
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 VAS = Treatment*Week + [Baseline VAS]*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 1.3.318.3.2: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 1.3.319.3.1: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	126	125	59.4 (23.09)		252	250	59.1 (25.01)		
Week 4		122	70.1 (18.94)			249	74.1 (18.34)		
Week 4 chg		122	10.3 (18.72)	11.01 (1.54)		249	15.0 (21.76)	15.00 (1.09)	3.99 (0.28, 7.69) 0.035 [0.19 (-0.03, 0.41)]
Week 8		120	71.2 (20.22)			237	75.5 (18.26)		
Week 8 chg		120	12.1 (23.42)	12.22 (1.55)		237	16.4 (23.73)	16.03 (1.10)	3.81 (0.07, 7.55) 0.046 [0.16 (-0.06, 0.38)]
Week 12		116	72.3 (21.36)			227	75.1 (18.28)		
Week 12 chg		116	12.1 (23.53)	12.65 (1.57)		227	16.4 (23.72)	15.70 (1.12)	3.04 (-0.74, 6.83) 0.115 [0.13 (-0.10, 0.35)]
Week 16		116	71.5 (21.22)			232	75.8 (18.84)		
Week 16 chg		116	12.4 (22.66)	12.51 (1.57)		232	17.0 (24.19)	16.27 (1.11)	3.77 (-0.01, 7.55) 0.051 [0.16 (-0.06, 0.38)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8731
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 VAS = Treatment*Week + [Baseline VAS]*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 1.3.319.3.1: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	118	117 58.5 (23.11)		236	234 58.3 (25.26)		
Week 4		115 69.9 (18.69)			234 73.5 (18.51)		
Week 4 chg		115 10.9 (18.35)	11.58 (1.60)		234 15.2 (22.10)	15.22 (1.12)	3.63 (-0.20, 7.46) 0.063 [0.17 (-0.05, 0.40)]
Week 8		113 71.0 (20.34)			221 75.1 (18.61)		
Week 8 chg		113 12.6 (23.47)	12.76 (1.61)		221 16.9 (24.11)	16.45 (1.14)	3.69 (-0.18, 7.56) 0.062 [0.15 (-0.07, 0.38)]
Week 12		109 72.3 (21.00)			212 74.8 (18.00)		
Week 12 chg		109 13.0 (23.47)	13.43 (1.62)		212 17.0 (23.35)	16.25 (1.16)	2.82 (-1.09, 6.73) 0.158 [0.12 (-0.11, 0.35)]
Week 16		109 71.0 (21.36)			217 75.3 (19.00)		
Week 16 chg		109 12.9 (22.51)	12.82 (1.62)		217 17.3 (24.30)	16.48 (1.15)	3.66 (-0.24, 7.57) 0.066 [0.15 (-0.08, 0.38)]

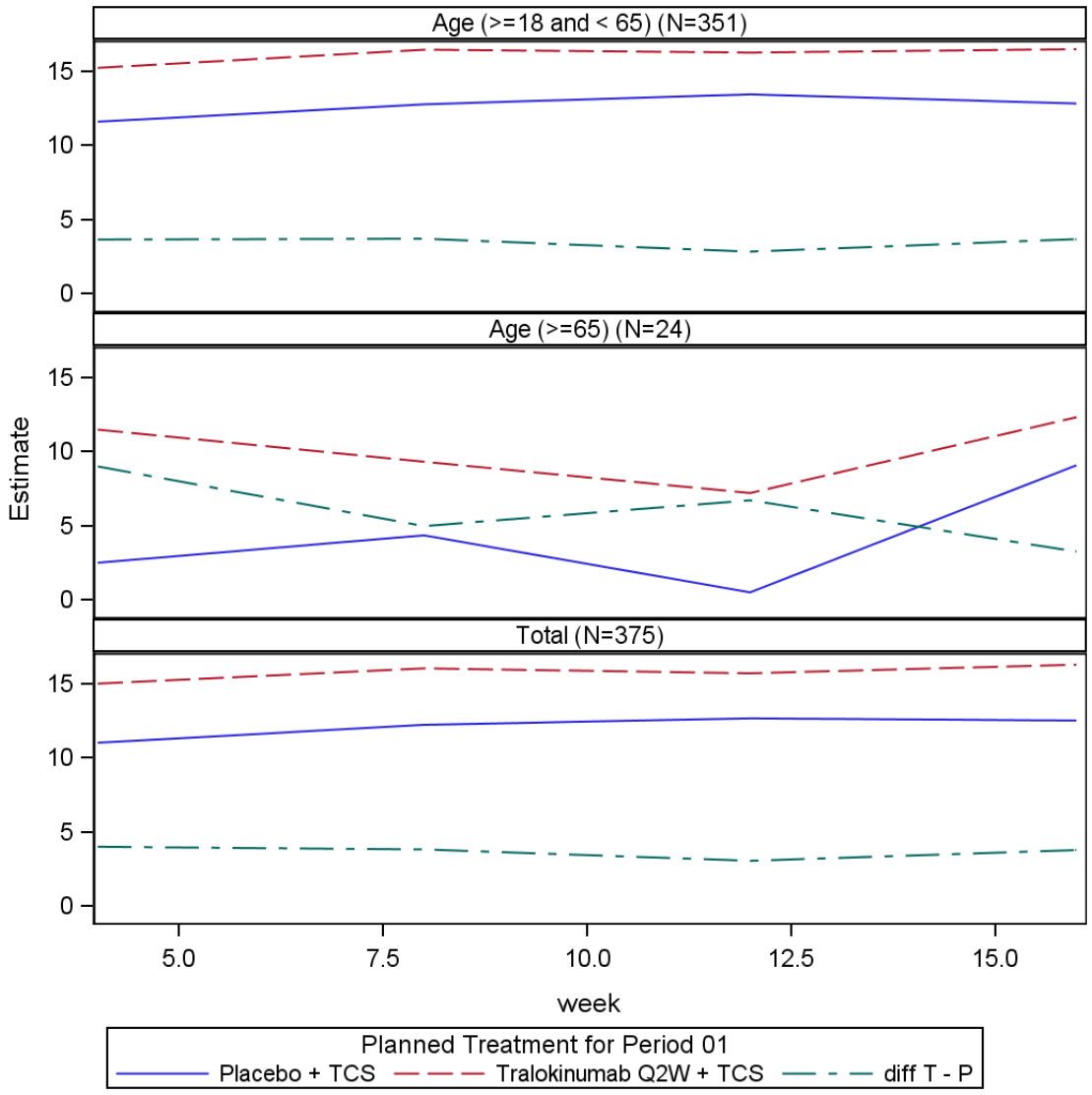
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8731
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*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 1.3.319.3.1: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 73.4 (18.97)		16	16 71.1 (17.43)		
Week 4		7 72.1 (24.34)			15 82.9 (13.00)		
Week 4 chg		7 1.4 (23.97)	2.49 (6.87)		15 11.0 (15.47)	11.48 (4.66)	8.99 (-7.79, 25.77) 0.288 [0.49 (-0.42, 1.40)]
Week 8		7 73.9 (19.40)			16 80.8 (11.70)		
Week 8 chg		7 2.9 (22.21)	4.34 (6.83)		16 9.8 (16.67)	9.30 (4.53)	4.96 (-11.6, 21.50) 0.550 [0.27 (-0.62, 1.16)]
Week 12		7 72.3 (28.52)			15 78.3 (22.39)		
Week 12 chg		7 -3.0 (20.22)	0.49 (6.84)		15 8.5 (28.09)	7.20 (4.66)	6.70 (-10.0, 23.43) 0.426 [0.26 (-0.64, 1.16)]
Week 16		7 79.6 (18.27)			15 83.9 (14.41)		
Week 16 chg		7 4.3 (25.39)	9.07 (6.84)		15 13.3 (23.11)	12.31 (4.65)	3.24 (-13.4, 19.92) 0.699 [0.14 (-0.76, 1.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8731
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 VAS = Treatment*Week + [Baseline VAS]*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 1.3.319.3.2: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 1.3.325.4.1: Total, Age group, EASI 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	88 (63.8)	15.3 (3.72;26.79)	1.3 (1.06; 1.62)	1.9 (1.16; 3.05)	0.0104	0.9424
Placebo + TCS	137	67 (48.9)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	84 (63.6)	15.2 (3.43;27.06)	1.3 (1.06; 1.63)	1.9 (1.14; 3.08)	0.0122	
Placebo + TCS	131	64 (48.9)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	4 (66.7)	44.7 (8.39;81.08)	2.7 (0.60;12.09)		0.1375	
Placebo + TCS	6	3 (50.0)					

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 Prior CSA use and baseline IGA.

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Table 1.3.326.4.1: Total, Age group, EASI 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	57 (41.3)	14.2 (3.21;25.12)	1.5 (1.09; 2.10)	1.9 (1.15; 3.21)	0.0123	0.6137
Placebo + TCS	137	38 (27.7)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	55 (41.7)	14.7 (3.47;26.00)	1.5 (1.10; 2.16)	2.0 (1.16; 3.29)	0.0112	
Placebo + TCS	131	36 (27.5)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	2 (33.3)	15.8 (-11.1;42.67)	1.6 (0.51; 5.00)		0.4142	
Placebo + TCS	6	2 (33.3)					

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 Prior CSA use and baseline IGA.

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Table 1.3.329.4.1: Total, Age group, SCORAD 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	40 (29.0)	16.9 (7.55;26.16)	2.4 (1.42; 3.96)	3.0 (1.58; 5.62)	0.0006	0.1333
Placebo + TCS	137	17 (12.4)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	39 (29.5)	18.4 (8.91;27.84)	2.6 (1.52; 4.50)	3.3 (1.72; 6.46)	0.0002	
Placebo + TCS	131	15 (11.5)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	1 (16.7)	-10.5 (-67.3;46.30)	0.6 (0.03;13.86)	0.6 (0.04; 8.32)	0.6949	
Placebo + TCS	6	2 (33.3)					

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 Prior CSA use and baseline IGA.

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Table 1.3.330.4.1: Total, Age group, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	134	62 (46.3)	9.7 (-1.99;21.41)	1.3 (0.95; 1.69)	1.5 (0.92; 2.44)	0.1068	0.1889
Placebo + TCS	135	49 (36.3)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	129	62 (48.1)	10.7 (-1.27;22.66)	1.3 (0.97; 1.71)	1.6 (0.95; 2.56)	0.0823	
Placebo + TCS	129	48 (37.2)					
Age (>=65)							
Tralokinumab Q2W + TCS	5	0 (0.0)	0.0 (0.00; 0.00)				
Placebo + TCS	6	1 (16.7)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

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Table 1.3.331.4.1: Total, Age group, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	137	85 (62.0)	11.3 (-0.46;23.02)	1.2 (0.99; 1.51)	1.6 (0.98; 2.55)	0.0614	0.2981
Placebo + TCS	136	69 (50.7)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	131	84 (64.1)	12.6 (0.73;24.52)	1.2 (1.01; 1.54)	1.7 (1.02; 2.76)	0.0393	
Placebo + TCS	130	67 (51.5)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	1 (16.7)	2.6 (-43.9;49.19)	1.2 (0.03;46.14)	1.2 (0.05;31.26)	0.9219	
Placebo + TCS	6	2 (33.3)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 3.

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Table 1.3.333.4.1: Total, Age group, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	135	105 (77.8)	18.9 (8.08;29.81)	1.3 (1.12; 1.56)	2.5 (1.44; 4.20)	0.0009	0.1728
Placebo + TCS	134	79 (59.0)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	129	101 (78.3)	20.7 (9.65;31.82)	1.4 (1.14; 1.62)	2.7 (1.55; 4.65)	0.0004	
Placebo + TCS	128	74 (57.8)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	4 (66.7)	-15.8 (-82.8;51.22)	0.8 (0.27; 2.36)	0.6 (0.06; 5.62)	0.6287	
Placebo + TCS	6	5 (83.3)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

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Table 1.3.335.4.1: Total, Age group, DLQI 0/1, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	32 (23.2)	6.9 (-2.56;16.32)	1.4 (0.87; 2.35)	1.5 (0.85; 2.81)	0.1545	0.3013
Placebo + TCS	136	22 (16.2)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	31 (23.5)	7.9 (-1.60;17.50)	1.5 (0.91; 2.55)	1.7 (0.90; 3.11)	0.1048	
Placebo + TCS	130	20 (15.4)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	1 (16.7)	-10.5 (-67.3;46.30)	0.6 (0.03;13.86)	0.6 (0.04; 8.32)	0.6949	
Placebo + TCS	6	2 (33.3)					

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 Prior CSA use and baseline IGA.

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Table 1.3.355.4.1: Total, Age group, EASI 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	96 (69.6)	16.8 (5.65;27.89)	1.3 (1.09; 1.59)	2.1 (1.27; 3.49)	0.0039	0.9986
Placebo + TCS	137	73 (53.3)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	92 (69.7)	16.6 (5.16;27.99)	1.3 (1.08; 1.59)	2.1 (1.24; 3.48)	0.0054	
Placebo + TCS	131	70 (53.4)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	4 (66.7)	44.7 (8.39;81.08)	2.7 (0.60;12.09)		0.1375	
Placebo + TCS	6	3 (50.0)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.3.356.4.1: Total, Age group, EASI 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	67 (48.6)	14.1 (2.87;25.40)	1.4 (1.06; 1.86)	1.8 (1.12; 3.04)	0.0160	0.2766
Placebo + TCS	137	48 (35.0)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	65 (49.2)	15.4 (3.82;26.92)	1.5 (1.09; 1.94)	1.9 (1.17; 3.23)	0.0107	
Placebo + TCS	131	45 (34.4)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	2 (33.3)	15.8 (-11.1;42.67)	1.6 (0.51; 5.00)		0.4142	
Placebo + TCS	6	3 (50.0)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.3.359.4.1: Total, Age group, SCORAD 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	53 (38.4)	20.6 (10.39;30.82)	2.1 (1.42; 3.22)	3.0 (1.68; 5.21)	0.0001	0.3924
Placebo + TCS	137	25 (18.2)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	51 (38.6)	21.5 (11.07;31.96)	2.2 (1.46; 3.45)	3.1 (1.73; 5.53)	<.0001	
Placebo + TCS	131	23 (17.6)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	2 (33.3)	15.8 (-11.1;42.67)	1.6 (0.51; 5.00)		0.4142	
Placebo + TCS	6	2 (33.3)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.3.360.4.1: Total, Age group, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	134	64 (47.8)	8.3 (-3.43;20.09)	1.2 (0.92; 1.60)	1.4 (0.87; 2.29)	0.1650	0.0601
Placebo + TCS	135	53 (39.3)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	129	64 (49.6)	9.8 (-2.24;21.80)	1.2 (0.95; 1.64)	1.5 (0.91; 2.45)	0.1115	
Placebo + TCS	129	51 (39.5)					
Age (>=65)							
Tralokinumab Q2W + TCS	5	0 (0.0)	-14.1 (-46.4;18.23)	0.0 (Not estimable)	0.0 (Not estimable)	0.4795	
Placebo + TCS	6	2 (33.3)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.3.361.4.1: Total, Age group, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	137	86 (62.8)	16.0 (4.45;27.60)	1.3 (1.08; 1.67)	1.9 (1.19; 3.16)	0.0078	0.2390
Placebo + TCS	136	64 (47.1)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	131	85 (64.9)	17.4 (5.71;29.18)	1.4 (1.10; 1.70)	2.1 (1.26; 3.44)	0.0044	
Placebo + TCS	130	62 (47.7)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	1 (16.7)	2.6 (-43.9;49.19)	1.2 (0.03;46.14)	1.2 (0.05;31.26)	0.9219	
Placebo + TCS	6	2 (33.3)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.3.363.4.1: Total, Age group, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	135	105 (77.8)	21.3 (10.39;32.18)	1.4 (1.16; 1.64)	2.7 (1.59; 4.63)	0.0002	0.9607
Placebo + TCS	134	76 (56.7)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	129	100 (77.5)	21.3 (10.12;32.54)	1.4 (1.15; 1.65)	2.7 (1.57; 4.64)	0.0003	
Placebo + TCS	128	72 (56.3)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	5 (83.3)	36.8 (-2.26;75.94)	1.7 (0.71; 4.25)		0.1698	
Placebo + TCS	6	4 (66.7)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.3.365.4.1: Total, Age group, DLQI 0/1, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	36 (26.1)	13.7 (4.62;22.81)	2.1 (1.25; 3.56)	2.5 (1.34; 4.85)	0.0038	0.5549
Placebo + TCS	136	17 (12.5)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	35 (26.5)	14.1 (4.74;23.45)	2.1 (1.25; 3.68)	2.6 (1.34; 4.99)	0.0039	
Placebo + TCS	130	16 (12.3)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	1 (16.7)	13.2 (-12.2;38.47)	2.0 (0.50; 8.00)		0.4795	
Placebo + TCS	6	1 (16.7)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.3.385.4.1: Total, Age group, SCORAD 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	13 (9.4)	4.5 (-1.61;10.59)	1.9 (0.78; 4.54)	2.0 (0.77; 5.17)	0.1522	0.1262
Placebo + TCS	137	7 (5.1)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	13 (9.8)	5.5 (-0.75;11.71)	2.2 (0.87; 5.56)	2.3 (0.87; 6.38)	0.0866	
Placebo + TCS	131	6 (4.6)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	0 (0.0)	-13.2 (-44.9;18.54)	0.0 (Not estimable)	0.0 (Not estimable)	0.4795	
Placebo + TCS	6	1 (16.7)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

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Table 1.3.389.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)											
Total											
Baseline	137	136	7.5 (1.37)			138	137	7.3 (1.45)			
Week 16		123	4.2 (2.30)				124	3.3 (2.05)			
Week 16 chg		122	-3.3 (2.36)	-3.21	(0.19)		123	-3.9 (2.06)	-3.98	(0.19)	-0.77 (-1.30, -0.24) 0.004 [-0.35 (-0.60, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0217
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.389.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)												
Baseline	131	130	7.5 (1.34)			132	131	7.3 (1.40)				
Week 16		117	4.2 (2.29)				118	3.3 (2.03)				
Week 16 chg		116	-3.3 (2.38)	-3.28	(0.19)		117	-4.1 (1.99)	-4.10	(0.19)	-0.82 (-1.36, -0.29) [-0.38 (-0.63, -0.12)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0217
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.389.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=65)								
Baseline	6	6 7.2 (2.17)		6	6 5.8 (1.98)			
Week 16		6 4.9 (2.63)			6 4.5 (2.25)			
Week 16 chg		6 -2.3 (1.83)	-1.91 (0.93)		6 -1.3 (1.76)	-1.63 (0.93)	0.28 (-3.17, 3.74) [0.16 (-0.97, 1.29)]	0.851

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0217
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.390.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 16		123 3.2 (2.41)			124 2.4 (2.16)		
Week 16 chg		122 -3.7 (2.29)	-3.50 (0.19)		123 -3.9 (2.32)	-4.03 (0.19)	-0.53 (-1.07, 0.01) 0.052 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0054
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.390.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	130 6.9 (1.62)		132	131 6.4 (2.09)		
Week 16		117 3.2 (2.40)			118 2.3 (2.15)		
Week 16 chg		116 -3.7 (2.31)	-3.55 (0.19)		117 -4.0 (2.16)	-4.16 (0.19)	-0.61 (-1.15, -0.08) 0.025 [-0.27 (-0.53, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0054
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.390.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 7.0 (2.34)		6	6 5.0 (2.30)		
Week 16		6 3.6 (2.67)			6 4.2 (1.82)		
Week 16 chg		6 -3.3 (2.07)	-2.44 (1.00)		6 -0.8 (3.24)	-1.69 (1.00)	0.74 (-2.98, 4.46) 0.651 [0.27 (-0.86, 1.41)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0054
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.391.4.1: Total, Age group, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
SCORAD Score								
Total								
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)			
Week 16		124 36.3 (18.78)			123 27.0 (16.90)			
Week 16 chg		124 -34.7 (19.94)	-34.36 (1.54)		123 -43.3 (19.46)	-43.61 (1.55)	-9.25 (-13.6, -4.94) [-0.47 (-0.72, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0479
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.391.4.1: Total, Age group, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	131 70.8 (12.81)		132	132 70.3 (12.06)		
Week 16		118 36.0 (17.61)			117 26.5 (16.64)		
Week 16 chg		118 -35.0 (19.51)	-34.67 (1.51)		117 -43.9 (19.01)	-44.12 (1.52)	-9.45 (-13.7, -5.23) <.001 [-0.49 (-0.75, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0479
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.391.4.1: Total, Age group, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=65)								
Baseline	6	6 72.3 (14.77)		6	6 68.4 (12.78)			
Week 16		6 42.5 (36.99)			6 36.8 (20.60)			
Week 16 chg		6 -29.8 (28.96)	-23.40 (10.33)		6 -31.6 (26.11)	-38.00 (10.33)	-14.60 (-50.9, 21.73) [-0.53 (-1.68, 0.62)]	0.374

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0479
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.392.4.1: Total, Age group, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 16		122 6.4 (5.60)			119 4.5 (3.87)		
Week 16 chg		120 -10.0 (6.54)	-9.61 (0.40)		118 -11.0 (5.99)	-11.29 (0.41)	-1.68 (-2.82, -0.55) 0.004 [-0.27 (-0.52, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0603
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.392.4.1: Total, Age group, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	131	128 16.5 (6.34)		132	131 16.0 (6.43)			
Week 16		116 6.5 (5.56)			113 4.3 (3.80)			
Week 16 chg		114 -10.1 (6.64)	-9.72 (0.41)		112 -11.3 (5.68)	-11.59 (0.41)	-1.88 (-3.02, -0.73) [-0.30 (-0.57, -0.04)]	0.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0603
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.392.4.1: Total, Age group, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=65)								
Baseline	6	6 13.7 (6.09)		6	6 12.3 (8.38)			
Week 16		6 5.7 (6.86)			6 7.2 (4.45)			
Week 16 chg		6 -8.0 (4.05)	-7.59 (2.08)		6 -5.2 (9.02)	-5.57 (2.08)	2.02 (-5.29, 9.34) [0.29 (-0.85, 1.43)]	0.534

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0603
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.393.4.1: Total, Age group, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 16		122 12.9 (7.67)			119 9.0 (5.53)			
Week 16 chg		120 -8.0 (8.09)	-8.10 (0.59)		116 -12.2 (6.39)	-12.12 (0.60)	-4.02 (-5.68, -2.36) [-0.55 (-0.81, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1808
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.393.4.1: Total, Age group, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)												
Baseline	131	128	20.9 (5.77)			132	129	21.3 (5.23)				
Week 16		116	13.0 (7.57)				113	8.8 (5.38)				
Week 16 chg		114	-8.0 (8.19)	-8.02	(0.60)		110	-12.4 (6.27)	-12.37	(0.61)	-4.35 (-6.03, -2.67) [-0.59 (-0.86, -0.33)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1808
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.393.4.1: Total, Age group, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=65)								
Baseline	6	6 19.3 (4.59)		6	6 21.3 (1.86)			
Week 16		6 10.5 (9.91)			6 13.3 (6.98)			
Week 16 chg		6 -8.8 (6.49)	-8.41 (3.58)		6 -8.0 (7.80)	-8.42 (3.58)	-0.00 (-12.4, 12.42) [-0.00 (-1.13, 1.13)]	0.999

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1808
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.395.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 16		122	69.3 (21.69)			119	75.7 (16.92)		
Week 16 chg		120	16.7 (26.74)	14.64 (1.75)		116	17.7 (22.49)	19.84 (1.78)	5.21 (0.28, 10.14) 0.039 [0.21 (-0.05, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0192
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.395.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)												
Baseline	131	128	52.2 (22.17)			132	129	56.4 (20.17)				
Week 16		116	70.1 (21.26)				113	76.5 (16.58)				
Week 16 chg		114	17.8 (25.98)	15.68	(1.75)		110	18.6 (22.57)	20.83	(1.78)	5.15 (0.20, 10.10) [0.21 (-0.05, 0.47)]	0.041

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0192
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.395.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=65)								
Baseline	6	6 58.0 (17.92)		6	6 60.3 (13.52)			
Week 16		6 54.2 (26.43)			6 60.5 (17.54)			
Week 16 chg		6 -3.8 (35.11)	-2.75 (10.72)		6 0.2 (11.57)	-0.91 (10.72)	1.84 (-35.2, 38.89) [0.07 (-1.06, 1.20)]	0.910

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0192
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.396.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss										
Total										
Baseline	137	137	6.7 (2.21)		138	138	6.7 (2.36)			
Week 16		124	2.7 (2.77)			123	1.9 (2.39)			
Week 16 chg		124	-4.1 (3.25)	-3.99 (0.23)		123	-4.7 (2.92)	-4.72 (0.23)	-0.73 (-1.36, -0.09) [-0.23 (-0.48, 0.02)]	0.025

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0185
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.396.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	131	131 6.7 (2.22)		132	132 6.7 (2.34)			
Week 16		118 2.7 (2.74)			117 1.8 (2.38)			
Week 16 chg		118 -4.1 (3.27)	-4.03 (0.23)		117 -4.8 (2.79)	-4.86 (0.23)	-0.83 (-1.47, -0.19) [-0.27 (-0.53, -0.02)]	0.011

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0185
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.396.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=65)								
Baseline	6	6 7.1 (1.94)		6	6 5.3 (2.64)			
Week 16		6 3.2 (3.57)			6 4.1 (1.69)			
Week 16 chg		6 -3.9 (3.30)	-2.65 (1.14)		6 -1.2 (3.51)	-2.43 (1.14)	0.22 (-3.95, 4.39) [0.07 (-1.07, 1.20)]	0.903

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0185
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.398.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 26		115	72.6 (20.73)			119	76.4 (17.30)		
Week 26 chg		113	20.5 (25.83)	18.74 (1.72)		116	19.5 (21.18)	21.31 (1.70)	2.56 (-2.22, 7.35) 0.292 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3786
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.398.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)									
Baseline	131	128	52.2 (22.17)		132	129	56.4 (20.17)		
Week 26		110	72.5 (20.97)			113	76.9 (17.51)		
Week 26 chg		108	20.8 (25.87)	18.94 (1.78)		110	20.2 (21.39)	22.08 (1.76)	3.14 (-1.81, 8.09) 0.213 [0.13 (-0.13, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3786
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.398.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=65)								
Baseline	6	6 58.0 (17.92)		6	6 60.3 (13.52)			
Week 26		5 74.6 (16.06)			6 66.8 (8.70)			
Week 26 chg		5 14.0 (26.94)	10.91 (4.72)		6 6.5 (11.26)	9.48 (4.06)	-1.44 (-17.5, 14.63) [-0.07 (-1.26, 1.11)]	0.834

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3786
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.401.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.56 (0.82)		138 -12.9 (10.72)	-13.28 (0.82)	-0.72 (-3.02, 1.57) 0.536 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.48 (0.83)		137 -18.8 (10.58)	-19.37 (0.82)	-1.88 (-4.18, 0.42) 0.109 [-0.17 (-0.41, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.42 (0.83)		134 -20.9 (11.93)	-21.43 (0.83)	-3.01 (-5.32, -0.70) 0.011 [-0.25 (-0.49, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.19 (0.83)		130 -22.5 (12.16)	-23.11 (0.83)	-3.92 (-6.23, -1.60) <.001 [-0.30 (-0.54, -0.06)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.50 (0.83)		130 -24.3 (11.55)	-24.96 (0.83)	-4.46 (-6.78, -2.14) <.001 [-0.35 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-20.99 (0.84)		128 -24.7 (12.40)	-25.11 (0.84)	-4.13 (-6.46, -1.80) <.001 [-0.31 (-0.56, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0532
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.401.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 11.2 (11.57)			127 7.0 (8.34)		
Week 14 chg		126 -22.8 (14.69)	-21.74 (0.84)		127 -25.1 (13.29)	-25.62 (0.84)	-3.87 (-6.21, -1.54) 0.001 [-0.28 (-0.52, -0.03)]
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.54 (0.84)		123 -25.9 (12.78)	-26.06 (0.84)	-3.52 (-5.86, -1.17) 0.003 [-0.25 (-0.50, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0532
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.401.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	131 33.8 (13.62)		132	132 31.9 (11.55)		
Week 2		131 20.9 (14.06)			132 18.9 (12.71)		
Week 2 chg		131 -12.9 (11.34)	-12.57 (0.82)		132 -13.0 (10.84)	-13.45 (0.82)	-0.88 (-3.16, 1.39) 0.445 [-0.08 (-0.32, 0.16)]
Week 4		128 15.6 (12.55)			131 12.8 (10.30)		
Week 4 chg		128 -18.3 (11.99)	-17.52 (0.82)		131 -19.0 (10.42)	-19.52 (0.82)	-1.99 (-4.28, 0.29) 0.087 [-0.18 (-0.42, 0.07)]
Week 6		126 14.7 (12.29)			128 10.8 (9.31)		
Week 6 chg		126 -19.3 (12.73)	-18.44 (0.83)		128 -21.1 (11.57)	-21.65 (0.82)	-3.21 (-5.50, -0.92) 0.006 [-0.26 (-0.51, -0.02)]
Week 8		127 13.8 (12.56)			124 9.2 (8.10)		
Week 8 chg		127 -20.1 (13.86)	-19.31 (0.82)		124 -22.8 (11.86)	-23.37 (0.83)	-4.06 (-6.35, -1.76) <.001 [-0.31 (-0.56, -0.07)]
Week 10		125 12.3 (11.42)			124 7.3 (7.20)		
Week 10 chg		125 -21.7 (13.91)	-20.68 (0.83)		124 -24.5 (11.41)	-25.18 (0.83)	-4.50 (-6.81, -2.20) <.001 [-0.35 (-0.60, -0.10)]
Week 12		123 11.8 (10.86)			122 7.4 (7.46)		
Week 12 chg		123 -22.4 (14.22)	-21.20 (0.83)		122 -24.8 (12.03)	-25.19 (0.83)	-3.99 (-6.30, -1.68) <.001 [-0.30 (-0.55, -0.05)]
Week 14		120 10.8 (10.68)			121 6.6 (7.73)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0532
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.401.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	120	-23.2 (14.41)	-22.12 (0.83)	121	-25.4 (12.82)	-25.84 (0.83)	-3.72 (-6.04, -1.40) [-0.27 (-0.53, -0.02)]	0.002
Week 16	118	10.1 (10.37)		117	6.1 (7.17)			
Week 16 chg	118	-24.2 (14.61)	-22.93 (0.84)	117	-26.0 (12.32)	-26.17 (0.84)	-3.24 (-5.57, -0.91) [-0.24 (-0.50, 0.02)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0532
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.401.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 34.8 (10.31)		6	6 35.5 (11.49)		
Week 2		6 22.3 (12.01)			6 26.4 (12.49)		
Week 2 chg		6 -12.5 (6.88)	-9.60 (5.46)		6 -9.1 (6.97)	-11.97 (5.46)	-2.37 (-19.6, 14.90) 0.770 [-0.34 (-1.48, 0.80)]
Week 4		6 17.8 (14.32)			6 20.0 (10.39)		
Week 4 chg		6 -17.0 (11.46)	-14.35 (5.46)		6 -15.5 (14.37)	-18.28 (5.46)	-3.93 (-21.2, 13.34) 0.629 [-0.30 (-1.44, 0.84)]
Week 6		6 16.5 (15.78)			6 19.1 (14.42)		
Week 6 chg		6 -18.3 (11.07)	-15.66 (5.46)		6 -16.4 (19.04)	-19.13 (5.46)	-3.47 (-20.7, 13.79) 0.669 [-0.22 (-1.36, 0.91)]
Week 8		6 18.0 (16.71)			6 18.4 (12.22)		
Week 8 chg		6 -16.8 (14.37)	-14.18 (5.46)		6 -17.2 (17.96)	-19.87 (5.46)	-5.68 (-22.9, 11.58) 0.487 [-0.35 (-1.49, 0.79)]
Week 10		6 17.8 (16.39)			6 15.6 (8.36)		
Week 10 chg		6 -16.9 (15.00)	-14.36 (5.46)		6 -19.9 (14.67)	-22.62 (5.46)	-8.26 (-25.5, 9.01) 0.318 [-0.56 (-1.71, 0.60)]
Week 12		5 18.2 (18.47)			6 12.7 (13.60)		
Week 12 chg		5 -17.9 (16.36)	-13.62 (5.66)		6 -22.9 (19.87)	-25.52 (5.46)	-11.90 (-29.3, 5.54) 0.164 [-0.65 (-1.86, 0.57)]
Week 14		6 20.6 (22.81)			6 14.9 (15.50)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0532
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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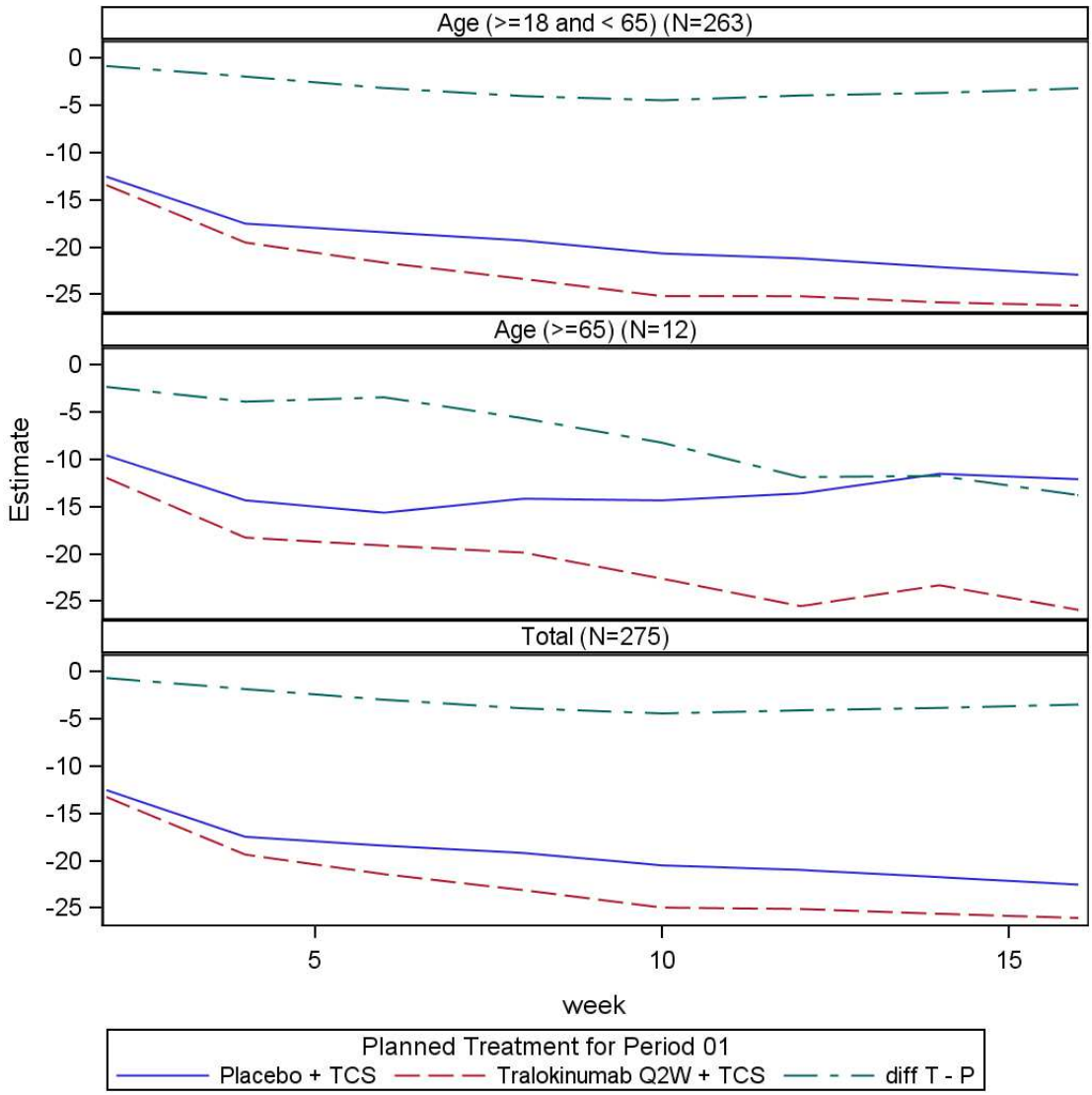
Table 1.3.401.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg		6 -14.2 (18.93)	-11.55 (5.46)		6 -20.6 (21.84)	-23.32 (5.46)	-11.77 (-29.0, 5.50) [-0.58 (-1.73, 0.58)]	0.163
Week 16		6 20.0 (24.05)			6 12.3 (13.57)			
Week 16 chg		6 -14.7 (19.67)	-12.12 (5.46)		6 -23.2 (21.25)	-25.92 (5.46)	-13.80 (-31.1, 3.47) [-0.67 (-1.84, 0.49)]	0.107

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0532
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.401.4.2: Total, Age group, change in EASI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.3.403.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)										
Total										
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)			
Week 1		135	6.3 (1.69)			136	6.0 (1.78)			
Week 1 chg		135	-1.1 (1.34)	-1.14 (0.17)		136	-1.2 (1.31)	-1.23 (0.17)	-0.08 (-0.56, 0.39) [-0.06 (-0.30, 0.18)]	0.732
Week 2		134	5.8 (1.97)			132	5.4 (2.11)			
Week 2 chg		134	-1.7 (1.78)	-1.67 (0.17)		132	-1.9 (1.67)	-1.92 (0.17)	-0.24 (-0.72, 0.24) [-0.14 (-0.38, 0.10)]	0.324
Week 3		133	5.3 (2.17)			131	4.8 (2.08)			
Week 3 chg		133	-2.2 (2.12)	-2.11 (0.17)		131	-2.5 (1.84)	-2.53 (0.17)	-0.42 (-0.90, 0.06) [-0.21 (-0.45, 0.03)]	0.088
Week 4		130	5.1 (2.25)			133	4.4 (2.14)			
Week 4 chg		130	-2.4 (2.14)	-2.29 (0.17)		133	-2.8 (1.92)	-2.87 (0.17)	-0.58 (-1.06, -0.10) [-0.28 (-0.53, -0.04)]	0.019
Week 5		131	4.9 (2.37)			129	4.2 (2.15)			
Week 5 chg		131	-2.6 (2.26)	-2.54 (0.17)		129	-3.1 (1.92)	-3.16 (0.17)	-0.62 (-1.10, -0.14) [-0.30 (-0.54, -0.05)]	0.012
Week 6		130	4.8 (2.35)			129	4.2 (2.16)			
Week 6 chg		130	-2.7 (2.25)	-2.58 (0.17)		129	-3.1 (1.99)	-3.14 (0.17)	-0.57 (-1.05, -0.08) [-0.27 (-0.51, -0.02)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1947
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.403.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	4.7 (2.24)		128	4.0 (2.13)		
Week 7 chg	129	-2.8 (2.25)	-2.73 (0.17)	128	-3.3 (2.05)	-3.38 (0.17)	-0.65 (-1.13, -0.16) 0.009 [-0.30 (-0.55, -0.05)]
Week 8	127	4.7 (2.32)		125	3.7 (2.10)		
Week 8 chg	127	-2.8 (2.27)	-2.73 (0.17)	125	-3.7 (1.96)	-3.64 (0.17)	-0.92 (-1.40, -0.43) <.001 [-0.43 (-0.68, -0.18)]
Week 9	127	4.6 (2.37)		127	3.6 (2.10)		
Week 9 chg	127	-2.9 (2.32)	-2.79 (0.17)	127	-3.7 (2.03)	-3.71 (0.17)	-0.92 (-1.40, -0.44) <.001 [-0.42 (-0.67, -0.17)]
Week 10	125	4.5 (2.42)		122	3.6 (2.11)		
Week 10 chg	125	-2.9 (2.39)	-2.87 (0.17)	122	-3.7 (1.93)	-3.70 (0.17)	-0.83 (-1.32, -0.35) <.001 [-0.38 (-0.63, -0.13)]
Week 11	128	4.4 (2.41)		126	3.5 (2.15)		
Week 11 chg	128	-3.1 (2.40)	-3.06 (0.17)	126	-3.7 (1.97)	-3.75 (0.17)	-0.70 (-1.18, -0.21) 0.005 [-0.32 (-0.56, -0.07)]
Week 12	123	4.4 (2.36)		121	3.5 (2.08)		
Week 12 chg	123	-3.1 (2.41)	-3.03 (0.17)	121	-3.8 (2.06)	-3.82 (0.17)	-0.80 (-1.28, -0.31) 0.001 [-0.35 (-0.61, -0.10)]
Week 13	116	4.3 (2.38)		120	3.3 (2.06)		
Week 13 chg	116	-3.3 (2.35)	-3.09 (0.18)	120	-4.0 (2.09)	-3.92 (0.17)	-0.84 (-1.32, -0.35) <.001 [-0.38 (-0.63, -0.12)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1947
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.403.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.13 (0.17)	123	-3.9 (2.12)	-3.85 (0.17)	-0.72 (-1.20, -0.23) [-0.32 (-0.57, -0.07)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.16 (0.17)	123	-4.0 (2.15)	-3.93 (0.17)	-0.76 (-1.25, -0.28) [-0.34 (-0.59, -0.09)]	0.002
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.10 (0.17)	122	-3.9 (2.06)	-3.93 (0.17)	-0.83 (-1.32, -0.35) [-0.38 (-0.63, -0.12)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1947
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.403.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)											
Baseline	131	130	7.5 (1.34)			132	131	7.3 (1.40)			
Week 1		129	6.4 (1.69)				130	6.1 (1.75)			
Week 1 chg		129	-1.1 (1.37)	-1.13	(0.17)		130	-1.3 (1.29)	-1.26	(0.17)	-0.13 (-0.62, 0.36) 0.600 [-0.10 (-0.34, 0.15)]
Week 2		128	5.8 (1.96)				126	5.4 (2.12)			
Week 2 chg		128	-1.7 (1.81)	-1.67	(0.18)		126	-2.0 (1.66)	-1.99	(0.18)	-0.32 (-0.81, 0.17) 0.197 [-0.18 (-0.43, 0.06)]
Week 3		127	5.3 (2.17)				125	4.8 (2.08)			
Week 3 chg		127	-2.2 (2.15)	-2.11	(0.18)		125	-2.6 (1.82)	-2.60	(0.18)	-0.49 (-0.98, -0.01) 0.047 [-0.25 (-0.50, -0.00)]
Week 4		124	5.1 (2.23)				127	4.4 (2.13)			
Week 4 chg		124	-2.4 (2.16)	-2.34	(0.18)		127	-2.9 (1.90)	-2.95	(0.18)	-0.61 (-1.10, -0.12) 0.015 [-0.30 (-0.55, -0.05)]
Week 5		125	4.9 (2.36)				123	4.1 (2.15)			
Week 5 chg		125	-2.7 (2.29)	-2.58	(0.18)		123	-3.2 (1.88)	-3.26	(0.18)	-0.68 (-1.17, -0.19) 0.006 [-0.33 (-0.58, -0.08)]
Week 6		124	4.8 (2.33)				123	4.2 (2.15)			
Week 6 chg		124	-2.7 (2.27)	-2.62	(0.18)		123	-3.2 (1.98)	-3.23	(0.18)	-0.61 (-1.09, -0.12) 0.015 [-0.28 (-0.54, -0.03)]
Week 7		123	4.6 (2.22)				122	3.9 (2.12)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1947
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.403.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	123	-2.9 (2.26)	-2.77 (0.18)	122	-3.4 (2.03)	-3.47 (0.18)	-0.70 (-1.19, -0.21) [-0.32 (-0.58, -0.07)]	0.005
Week 8	121	4.7 (2.28)		119	3.6 (2.10)			
Week 8 chg	121	-2.9 (2.27)	-2.78 (0.18)	119	-3.8 (1.93)	-3.73 (0.18)	-0.95 (-1.45, -0.46) [-0.45 (-0.71, -0.20)]	<.001
Week 9	121	4.6 (2.35)		121	3.6 (2.09)			
Week 9 chg	121	-2.9 (2.34)	-2.83 (0.18)	121	-3.8 (1.97)	-3.81 (0.18)	-0.98 (-1.47, -0.49) [-0.45 (-0.71, -0.20)]	<.001
Week 10	119	4.5 (2.38)		116	3.6 (2.09)			
Week 10 chg	119	-3.0 (2.39)	-2.92 (0.18)	116	-3.8 (1.86)	-3.82 (0.18)	-0.89 (-1.38, -0.40) [-0.42 (-0.67, -0.16)]	<.001
Week 11	122	4.3 (2.37)		120	3.5 (2.13)			
Week 11 chg	122	-3.2 (2.41)	-3.12 (0.18)	120	-3.9 (1.91)	-3.87 (0.18)	-0.75 (-1.24, -0.26) [-0.34 (-0.60, -0.09)]	0.003
Week 12	118	4.4 (2.38)		115	3.5 (2.05)			
Week 12 chg	118	-3.1 (2.43)	-3.05 (0.18)	115	-3.9 (2.01)	-3.94 (0.18)	-0.89 (-1.38, -0.40) [-0.40 (-0.66, -0.14)]	<.001
Week 13	111	4.3 (2.38)		114	3.2 (2.04)			
Week 13 chg	111	-3.3 (2.36)	-3.13 (0.18)	114	-4.1 (2.04)	-4.03 (0.18)	-0.90 (-1.39, -0.40) [-0.41 (-0.67, -0.14)]	<.001
Week 14	118	4.3 (2.37)		118	3.3 (2.12)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1947
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.403.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	118	-3.3 (2.35)	-3.17 (0.18)	118	-4.0 (2.09)	-3.95 (0.18)	-0.78 (-1.27, -0.29) [-0.35 (-0.61, -0.09)]	0.002
Week 15	117	4.2 (2.30)		117	3.3 (2.11)			
Week 15 chg	117	-3.4 (2.34)	-3.21 (0.18)	117	-4.1 (2.09)	-4.03 (0.18)	-0.82 (-1.32, -0.33) [-0.37 (-0.63, -0.11)]	0.001
Week 16	115	4.2 (2.28)		116	3.3 (2.03)			
Week 16 chg	115	-3.4 (2.36)	-3.16 (0.18)	116	-4.1 (1.99)	-4.05 (0.18)	-0.89 (-1.38, -0.39) [-0.41 (-0.67, -0.15)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1947
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.403.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 7.2 (2.17)		6	6 5.8 (1.98)		
Week 1		6 5.8 (1.89)			6 5.5 (2.50)		
Week 1 chg		6 -1.4 (0.66)	-1.10 (0.84)		6 -0.3 (1.46)	-0.62 (0.83)	0.48 (-2.44, 3.39) 0.721 [0.42 (-0.72, 1.56)]
Week 2		6 5.2 (2.29)			6 5.5 (1.98)		
Week 2 chg		6 -2.0 (1.03)	-1.66 (0.84)		6 -0.3 (1.14)	-0.60 (0.83)	1.06 (-1.86, 3.98) 0.434 [0.97 (-0.22, 2.17)]
Week 3		6 4.8 (2.21)			6 5.0 (2.28)		
Week 3 chg		6 -2.4 (1.36)	-2.04 (0.84)		6 -0.8 (1.29)	-1.09 (0.83)	0.96 (-1.96, 3.87) 0.479 [0.72 (-0.45, 1.89)]
Week 4		6 5.7 (2.89)			6 4.8 (2.51)		
Week 4 chg		6 -1.4 (1.65)	-1.25 (0.84)		6 -1.0 (1.40)	-1.15 (0.83)	0.11 (-2.81, 3.02) 0.936 [0.07 (-1.06, 1.20)]
Week 5		6 5.2 (2.75)			6 4.9 (2.33)		
Week 5 chg		6 -2.0 (1.57)	-1.72 (0.84)		6 -0.9 (1.44)	-1.13 (0.83)	0.59 (-2.33, 3.51) 0.658 [0.39 (-0.75, 1.54)]
Week 6		6 5.3 (2.90)			6 4.6 (2.41)		
Week 6 chg		6 -1.9 (1.81)	-1.68 (0.84)		6 -1.2 (1.07)	-1.43 (0.83)	0.25 (-2.67, 3.17) 0.851 [0.17 (-0.97, 1.30)]
Week 7		6 5.1 (2.81)			6 4.6 (2.35)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1947
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.403.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	6	-2.1 (2.10)	-1.80 (0.84)	6	-1.2 (1.20)	-1.45 (0.83)	0.35 (-2.57, 3.27) 0.795 [0.20 (-0.93, 1.34)]
Week 8	6	5.3 (3.23)		6	4.2 (2.23)		
Week 8 chg	6	-1.9 (2.23)	-1.71 (0.84)	6	-1.6 (1.08)	-1.77 (0.83)	-0.07 (-2.98, 2.85) 0.960 [-0.04 (-1.17, 1.09)]
Week 9	6	5.0 (2.95)		6	4.5 (2.30)		
Week 9 chg	6	-2.2 (2.05)	-1.92 (0.84)	6	-1.3 (1.66)	-1.58 (0.83)	0.34 (-2.57, 3.26) 0.796 [0.18 (-0.95, 1.32)]
Week 10	6	5.1 (3.33)		6	4.6 (2.44)		
Week 10 chg	6	-2.1 (2.23)	-1.84 (0.84)	6	-1.2 (1.73)	-1.40 (0.83)	0.44 (-2.48, 3.36) 0.742 [0.22 (-0.91, 1.36)]
Week 11	6	5.1 (3.34)		6	4.6 (2.54)		
Week 11 chg	6	-2.1 (2.07)	-1.93 (0.84)	6	-1.2 (1.45)	-1.33 (0.83)	0.60 (-2.32, 3.52) 0.654 [0.34 (-0.80, 1.48)]
Week 12	5	3.6 (2.02)		6	4.7 (2.55)		
Week 12 chg	5	-3.0 (2.09)	-2.56 (0.85)	6	-1.2 (1.38)	-1.44 (0.83)	1.12 (-1.80, 4.04) 0.411 [0.64 (-0.57, 1.86)]
Week 13	5	4.2 (2.63)		6	4.5 (2.29)		
Week 13 chg	5	-2.5 (2.17)	-2.03 (0.85)	6	-1.4 (1.22)	-1.59 (0.83)	0.44 (-2.48, 3.36) 0.740 [0.26 (-0.93, 1.45)]
Week 14	5	4.0 (2.93)		5	4.4 (2.50)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1947
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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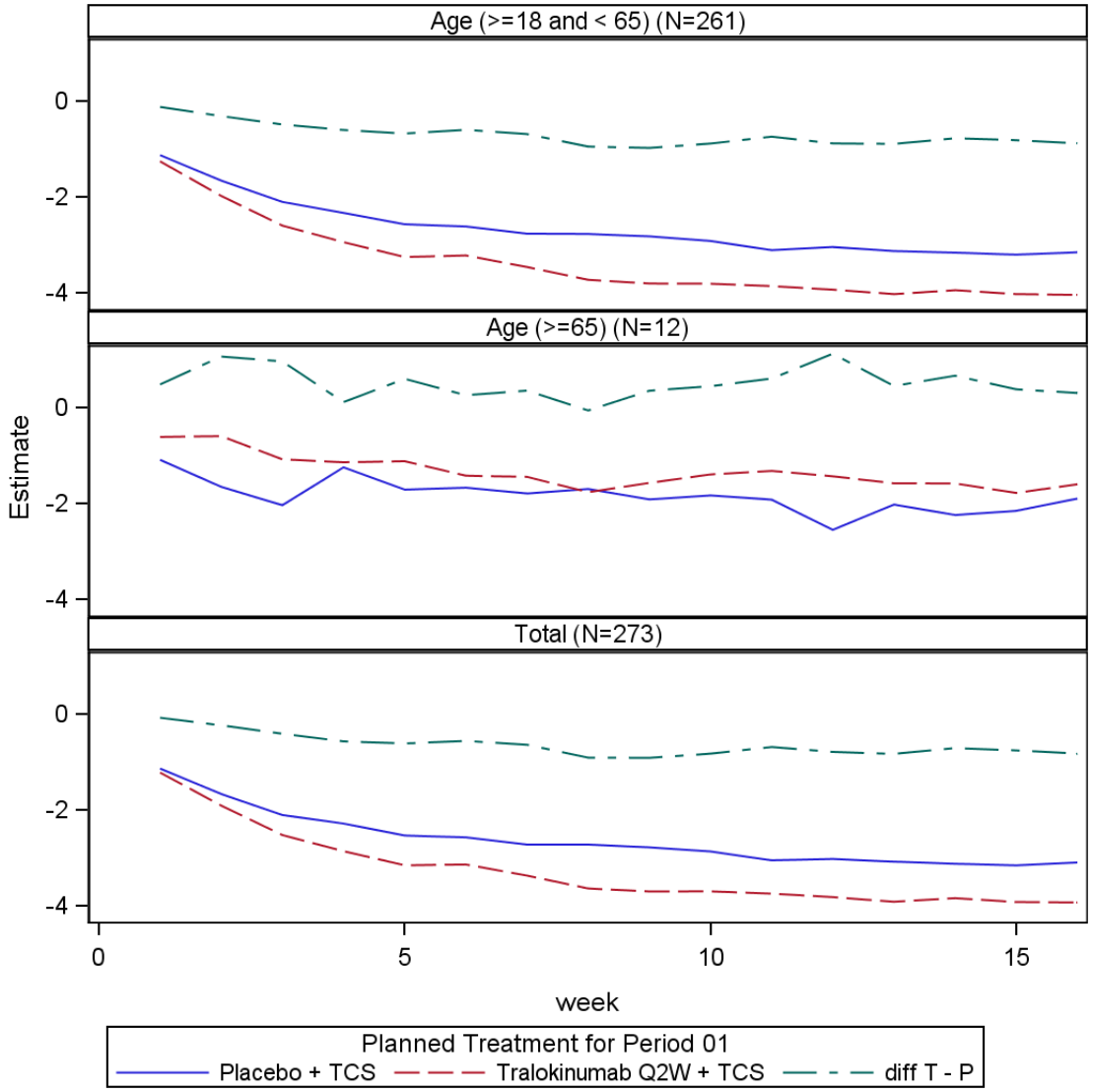
Table 1.3.403.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	5	-2.7 (2.02)	-2.25 (0.85)	5	-1.6 (1.37)	-1.59 (0.84)	0.66 (-2.27, 3.59) [0.38 (-0.87, 1.63)]	0.626
Week 15	6	4.6 (2.81)		6	4.4 (2.03)			
Week 15 chg	6	-2.5 (1.89)	-2.16 (0.84)	6	-1.4 (1.74)	-1.79 (0.83)	0.37 (-2.54, 3.29) [0.21 (-0.93, 1.34)]	0.779
Week 16	6	4.9 (2.63)		6	4.5 (2.25)			
Week 16 chg	6	-2.3 (1.83)	-1.90 (0.84)	6	-1.3 (1.76)	-1.61 (0.83)	0.30 (-2.62, 3.22) [0.17 (-0.97, 1.30)]	0.823

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1947
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.403.4.2: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.3.405.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)			
Week 1		135 5.8 (2.01)			136 5.2 (2.21)			
Week 1 chg		135 -1.1 (1.50)	-1.07 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.08 (-0.58, 0.42) [-0.05 (-0.29, 0.18)]	0.756
Week 2		134 5.2 (2.29)			132 4.5 (2.45)			
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.18)	-0.18 (-0.68, 0.33) [-0.09 (-0.33, 0.15)]	0.493
Week 3		133 4.7 (2.36)			131 3.9 (2.35)			
Week 3 chg		133 -2.2 (2.17)	-2.13 (0.18)		131 -2.4 (2.01)	-2.49 (0.18)	-0.36 (-0.86, 0.14) [-0.17 (-0.41, 0.07)]	0.160
Week 4		130 4.5 (2.48)			133 3.6 (2.39)			
Week 4 chg		130 -2.4 (2.23)	-2.26 (0.18)		133 -2.7 (2.06)	-2.79 (0.18)	-0.53 (-1.03, -0.03) [-0.25 (-0.49, -0.01)]	0.038
Week 5		131 4.2 (2.55)			129 3.3 (2.42)			
Week 5 chg		131 -2.7 (2.37)	-2.56 (0.18)		129 -3.0 (2.16)	-3.14 (0.18)	-0.58 (-1.08, -0.07) [-0.25 (-0.50, -0.01)]	0.024
Week 6		130 4.2 (2.52)			129 3.3 (2.42)			
Week 6 chg		130 -2.7 (2.36)	-2.53 (0.18)		129 -3.1 (2.24)	-3.20 (0.18)	-0.67 (-1.17, -0.17) [-0.29 (-0.54, -0.05)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0016
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.405.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	3.9 (2.43)		128	3.1 (2.37)			
Week 7 chg	129	-3.0 (2.38)	-2.81 (0.18)	128	-3.3 (2.28)	-3.41 (0.18)	-0.60 (-1.10, -0.10) [-0.26 (-0.50, -0.01)]	0.020
Week 8	127	3.9 (2.46)		125	2.8 (2.29)			
Week 8 chg	127	-3.0 (2.32)	-2.79 (0.18)	125	-3.6 (2.26)	-3.65 (0.18)	-0.86 (-1.36, -0.35) [-0.37 (-0.62, -0.12)]	<.001
Week 9	127	3.8 (2.49)		127	2.6 (2.22)			
Week 9 chg	127	-3.1 (2.33)	-2.92 (0.18)	127	-3.7 (2.23)	-3.83 (0.18)	-0.91 (-1.41, -0.40) [-0.40 (-0.65, -0.15)]	<.001
Week 10	125	3.7 (2.54)		122	2.7 (2.29)			
Week 10 chg	125	-3.2 (2.40)	-3.04 (0.18)	122	-3.7 (2.29)	-3.82 (0.18)	-0.79 (-1.29, -0.28) [-0.33 (-0.59, -0.08)]	0.002
Week 11	128	3.6 (2.46)		126	2.6 (2.22)			
Week 11 chg	128	-3.3 (2.40)	-3.15 (0.18)	126	-3.8 (2.26)	-3.89 (0.18)	-0.75 (-1.25, -0.24) [-0.32 (-0.57, -0.07)]	0.004
Week 12	123	3.5 (2.44)		121	2.5 (2.21)			
Week 12 chg	123	-3.4 (2.45)	-3.18 (0.18)	121	-3.8 (2.38)	-4.01 (0.18)	-0.82 (-1.33, -0.31) [-0.34 (-0.59, -0.09)]	0.002
Week 13	116	3.4 (2.40)		120	2.3 (2.13)			
Week 13 chg	116	-3.6 (2.32)	-3.32 (0.18)	120	-3.9 (2.26)	-4.05 (0.18)	-0.74 (-1.25, -0.23) [-0.32 (-0.58, -0.06)]	0.005

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0016
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.3.405.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	3.3 (2.42)		123	2.4 (2.18)			
Week 14 chg	123	-3.5 (2.33)	-3.36 (0.18)	123	-3.9 (2.27)	-4.03 (0.18)	-0.67 (-1.18, -0.16) [-0.29 (-0.54, -0.04)]	0.010
Week 15	123	3.3 (2.47)		123	2.4 (2.18)			
Week 15 chg	123	-3.7 (2.35)	-3.42 (0.18)	123	-3.9 (2.35)	-4.08 (0.18)	-0.66 (-1.16, -0.15) [-0.28 (-0.53, -0.03)]	0.011
Week 16	121	3.2 (2.40)		122	2.5 (2.17)			
Week 16 chg	121	-3.7 (2.28)	-3.41 (0.18)	122	-3.9 (2.32)	-4.06 (0.18)	-0.65 (-1.16, -0.14) [-0.28 (-0.54, -0.03)]	0.012

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0016
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.405.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)										
Baseline	131	130	6.9 (1.62)		132	131	6.4 (2.09)			
Week 1		129	5.8 (2.02)			130	5.2 (2.20)			
Week 1 chg		129	-1.1 (1.52)	-1.06 (0.18)		130	-1.1 (1.44)	-1.18 (0.18)	-0.11 (-0.62, 0.39) [-0.08 (-0.32, 0.17)]	0.658
Week 2		128	5.2 (2.30)			126	4.5 (2.47)			
Week 2 chg		128	-1.7 (2.02)	-1.67 (0.18)		126	-1.8 (1.78)	-1.90 (0.18)	-0.24 (-0.74, 0.27) [-0.12 (-0.37, 0.12)]	0.363
Week 3		127	4.7 (2.37)			125	3.9 (2.37)			
Week 3 chg		127	-2.2 (2.19)	-2.12 (0.18)		125	-2.5 (1.98)	-2.55 (0.18)	-0.43 (-0.94, 0.08) [-0.20 (-0.45, 0.04)]	0.099
Week 4		124	4.5 (2.47)			127	3.6 (2.40)			
Week 4 chg		124	-2.4 (2.26)	-2.29 (0.18)		127	-2.8 (2.01)	-2.87 (0.18)	-0.58 (-1.09, -0.07) [-0.27 (-0.52, -0.02)]	0.026
Week 5		125	4.2 (2.56)			123	3.3 (2.42)			
Week 5 chg		125	-2.7 (2.41)	-2.57 (0.18)		123	-3.2 (2.08)	-3.24 (0.18)	-0.66 (-1.17, -0.15) [-0.29 (-0.54, -0.04)]	0.011
Week 6		124	4.2 (2.52)			123	3.2 (2.43)			
Week 6 chg		124	-2.7 (2.39)	-2.55 (0.18)		123	-3.2 (2.19)	-3.30 (0.18)	-0.75 (-1.26, -0.24) [-0.33 (-0.58, -0.08)]	0.004
Week 7		123	3.9 (2.44)			122	3.0 (2.36)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0016
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.3.405.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	123	-3.0 (2.41)	-2.82 (0.18)	122	-3.4 (2.20)	-3.51 (0.18)	-0.69 (-1.20, -0.18) [-0.30 (-0.55, -0.05)]	0.008
Week 8	121	3.9 (2.44)		119	2.7 (2.29)			
Week 8 chg	121	-3.0 (2.34)	-2.84 (0.18)	119	-3.7 (2.17)	-3.77 (0.18)	-0.93 (-1.44, -0.42) [-0.41 (-0.67, -0.16)]	<.001
Week 9	121	3.8 (2.48)		121	2.6 (2.20)			
Week 9 chg	121	-3.1 (2.36)	-2.96 (0.18)	121	-3.9 (2.14)	-3.96 (0.18)	-0.99 (-1.50, -0.48) [-0.44 (-0.70, -0.19)]	<.001
Week 10	119	3.7 (2.52)		116	2.6 (2.26)			
Week 10 chg	119	-3.2 (2.42)	-3.09 (0.18)	116	-3.9 (2.12)	-3.97 (0.18)	-0.88 (-1.40, -0.37) [-0.39 (-0.65, -0.13)]	<.001
Week 11	122	3.6 (2.43)		120	2.5 (2.20)			
Week 11 chg	122	-3.3 (2.42)	-3.20 (0.18)	120	-3.9 (2.15)	-4.02 (0.18)	-0.83 (-1.34, -0.31) [-0.36 (-0.61, -0.11)]	0.002
Week 12	118	3.5 (2.48)		115	2.4 (2.18)			
Week 12 chg	118	-3.4 (2.47)	-3.20 (0.18)	115	-4.0 (2.24)	-4.14 (0.18)	-0.93 (-1.45, -0.42) [-0.40 (-0.65, -0.14)]	<.001
Week 13	111	3.4 (2.43)		114	2.2 (2.11)			
Week 13 chg	111	-3.6 (2.35)	-3.35 (0.18)	114	-4.1 (2.16)	-4.17 (0.18)	-0.82 (-1.34, -0.31) [-0.37 (-0.63, -0.10)]	0.002
Week 14	118	3.4 (2.45)		118	2.3 (2.18)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0016
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.405.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	118	-3.5 (2.37)	-3.38 (0.18)	118	-4.0 (2.18)	-4.14 (0.18)	-0.76 (-1.27, -0.25) [-0.33 (-0.59, -0.08)]	0.004
Week 15	117	3.3 (2.47)		117	2.3 (2.17)			
Week 15 chg	117	-3.7 (2.38)	-3.45 (0.18)	117	-4.1 (2.18)	-4.20 (0.18)	-0.75 (-1.26, -0.24) [-0.33 (-0.59, -0.07)]	0.004
Week 16	115	3.2 (2.39)		116	2.4 (2.15)			
Week 16 chg	115	-3.7 (2.29)	-3.45 (0.18)	116	-4.1 (2.17)	-4.19 (0.18)	-0.74 (-1.25, -0.23) [-0.33 (-0.59, -0.07)]	0.005

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0016
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.405.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 7.0 (2.34)		6	6 5.0 (2.30)		
Week 1		6 5.5 (1.90)			6 4.6 (2.56)		
Week 1 chg		6 -1.4 (0.85)	-1.06 (0.89)		6 -0.4 (1.61)	-0.77 (0.88)	0.29 (-2.77, 3.34) 0.839 [0.22 (-0.91, 1.36)]
Week 2		6 5.0 (2.31)			6 4.7 (2.19)		
Week 2 chg		6 -1.9 (1.14)	-1.53 (0.89)		6 -0.4 (1.68)	-0.74 (0.88)	0.79 (-2.27, 3.84) 0.580 [0.55 (-0.60, 1.70)]
Week 3		6 4.3 (2.30)			6 4.3 (2.05)		
Week 3 chg		6 -2.6 (1.71)	-2.03 (0.89)		6 -0.8 (2.11)	-1.32 (0.88)	0.72 (-2.34, 3.77) 0.615 [0.37 (-0.77, 1.51)]
Week 4		6 5.0 (2.84)			6 4.2 (2.12)		
Week 4 chg		6 -1.9 (1.34)	-1.49 (0.89)		6 -0.8 (2.35)	-1.20 (0.88)	0.28 (-2.77, 3.34) 0.840 [0.15 (-0.98, 1.28)]
Week 5		6 4.3 (2.46)			6 4.5 (2.29)		
Week 5 chg		6 -2.6 (1.47)	-2.05 (0.89)		6 -0.6 (2.55)	-1.09 (0.88)	0.96 (-2.09, 4.02) 0.500 [0.46 (-0.68, 1.61)]
Week 6		6 4.5 (2.76)			6 4.3 (2.21)		
Week 6 chg		6 -2.5 (1.47)	-2.05 (0.89)		6 -0.7 (2.18)	-1.09 (0.88)	0.96 (-2.09, 4.02) 0.501 [0.52 (-0.63, 1.67)]
Week 7		6 4.0 (2.37)			6 4.3 (2.26)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0016
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.3.405.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	6	-3.0 (1.91)	-2.35 (0.89)	6	-0.7 (2.39)	-1.29 (0.88)	1.06 (-1.99, 4.11) 0.460 [0.49 (-0.66, 1.64)]
Week 8	6	4.5 (2.98)		6	4.2 (1.97)		
Week 8 chg	6	-2.4 (1.91)	-1.86 (0.89)	6	-0.8 (2.45)	-1.30 (0.88)	0.56 (-2.49, 3.62) 0.691 [0.26 (-0.88, 1.39)]
Week 9	6	4.3 (2.82)		6	4.2 (1.98)		
Week 9 chg	6	-2.7 (1.88)	-2.14 (0.89)	6	-0.8 (2.25)	-1.28 (0.88)	0.86 (-2.19, 3.92) 0.546 [0.42 (-0.73, 1.56)]
Week 10	6	4.5 (3.16)		6	4.8 (2.20)		
Week 10 chg	6	-2.5 (1.92)	-1.91 (0.89)	6	-0.2 (3.01)	-0.77 (0.88)	1.14 (-1.92, 4.19) 0.429 [0.45 (-0.69, 1.60)]
Week 11	6	4.3 (3.18)		6	4.3 (2.08)		
Week 11 chg	6	-2.6 (1.84)	-2.16 (0.89)	6	-0.7 (2.43)	-1.17 (0.88)	0.98 (-2.07, 4.04) 0.491 [0.46 (-0.69, 1.60)]
Week 12	5	2.7 (1.27)		6	4.4 (2.15)		
Week 12 chg	5	-3.7 (2.12)	-2.70 (0.90)	6	-0.6 (2.90)	-1.44 (0.88)	1.26 (-1.80, 4.32) 0.382 [0.49 (-0.72, 1.69)]
Week 13	5	3.1 (1.63)		6	4.1 (1.75)		
Week 13 chg	5	-3.4 (1.79)	-2.47 (0.90)	6	-1.0 (2.36)	-1.59 (0.88)	0.88 (-2.18, 3.94) 0.539 [0.41 (-0.79, 1.61)]
Week 14	5	2.8 (1.62)		5	3.9 (1.81)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0016
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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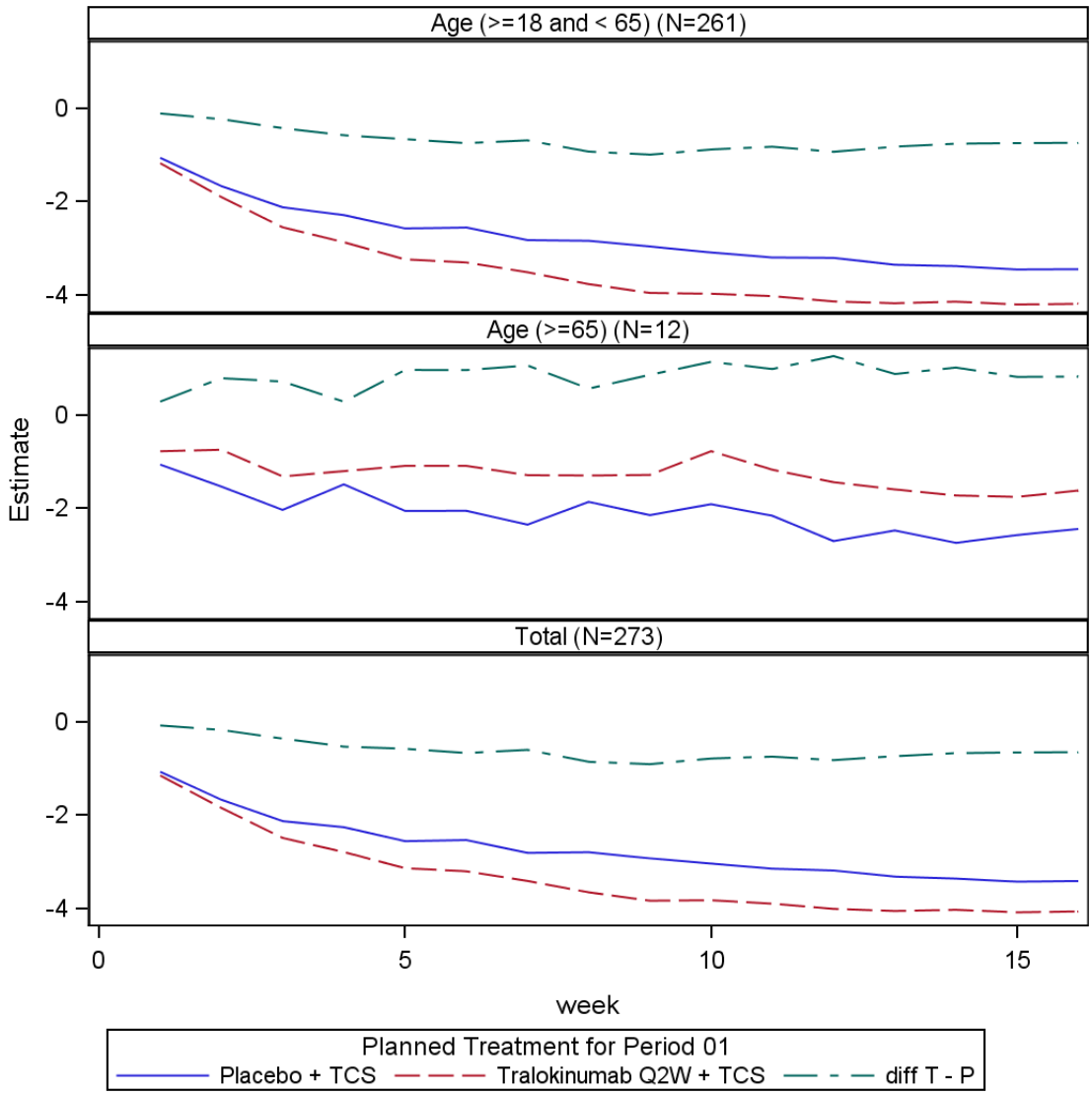
Table 1.3.405.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	5	-3.7 (1.48)	-2.74 (0.90)	5	-1.2 (2.85)	-1.72 (0.90)	1.01 (-2.06, 4.09) 0.483 [0.45 (-0.81, 1.70)]
Week 15	6	3.5 (2.76)		6	4.1 (1.86)		
Week 15 chg	6	-3.5 (1.96)	-2.57 (0.89)	6	-0.9 (3.51)	-1.75 (0.88)	0.82 (-2.24, 3.87) 0.567 [0.29 (-0.85, 1.42)]
Week 16	6	3.6 (2.67)		6	4.2 (1.82)		
Week 16 chg	6	-3.3 (2.07)	-2.44 (0.89)	6	-0.8 (3.24)	-1.62 (0.88)	0.82 (-2.23, 3.88) 0.564 [0.30 (-0.84, 1.44)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0016
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.405.4.2: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.3.407.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.22 (1.49)		138 -20.9 (16.72)	-21.06 (1.48)	-3.84 (-7.97, 0.30) 0.069 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.25 (1.50)		137 -30.8 (17.25)	-31.00 (1.49)	-4.75 (-8.90, -0.60) 0.025 [-0.27 (-0.51, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.77 (1.50)		134 -34.3 (17.49)	-34.45 (1.49)	-7.67 (-11.8, -3.51) <.001 [-0.42 (-0.66, -0.18)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.63 (1.50)		130 -36.6 (18.48)	-36.80 (1.50)	-8.16 (-12.3, -3.99) <.001 [-0.43 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.78 (1.50)		130 -38.5 (19.49)	-38.59 (1.50)	-7.81 (-12.0, -3.63) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.51 (1.51)		128 -39.5 (18.74)	-39.57 (1.51)	-8.06 (-12.3, -3.87) <.001 [-0.42 (-0.67, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2177
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.407.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	36.0 (19.61)		127	28.3 (17.87)		
Week 14 chg	126	-34.8 (20.31)	-34.13 (1.52)	127	-41.8 (20.11)	-41.35 (1.51)	-7.22 (-11.4, -3.01) <.001 [-0.36 (-0.61, -0.11)]
Week 16	124	36.3 (18.78)		123	27.0 (16.90)		
Week 16 chg	124	-34.7 (19.94)	-33.86 (1.52)	123	-43.3 (19.46)	-42.65 (1.52)	-8.79 (-13.0, -4.57) <.001 [-0.45 (-0.70, -0.19)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2177
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.407.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	131 70.8 (12.81)		132	132 70.3 (12.06)		
Week 2		131 53.3 (17.53)			132 48.9 (18.16)		
Week 2 chg		131 -17.5 (16.18)	-17.32 (1.49)		132 -21.4 (16.67)	-21.49 (1.48)	-4.18 (-8.31, -0.05) 0.047 [-0.25 (-0.50, -0.01)]
Week 4		128 43.7 (18.12)			131 38.6 (17.59)		
Week 4 chg		128 -26.9 (18.26)	-26.34 (1.50)		131 -31.5 (17.06)	-31.56 (1.49)	-5.22 (-9.37, -1.08) 0.014 [-0.30 (-0.54, -0.05)]
Week 6		126 43.3 (18.43)			128 35.6 (16.65)		
Week 6 chg		126 -27.5 (19.01)	-26.89 (1.50)		128 -34.5 (17.44)	-34.60 (1.49)	-7.71 (-11.9, -3.55) <.001 [-0.42 (-0.67, -0.17)]
Week 8		127 41.3 (19.30)			124 32.7 (16.64)		
Week 8 chg		127 -29.3 (19.46)	-28.93 (1.50)		124 -37.4 (17.96)	-37.46 (1.50)	-8.53 (-12.7, -4.36) <.001 [-0.46 (-0.71, -0.20)]
Week 10		125 39.0 (19.39)			124 30.4 (17.54)		
Week 10 chg		125 -31.7 (20.95)	-31.01 (1.50)		124 -39.5 (18.63)	-39.51 (1.50)	-8.51 (-12.7, -4.33) <.001 [-0.43 (-0.68, -0.18)]
Week 12		123 38.4 (17.44)			122 30.0 (17.26)		
Week 12 chg		123 -32.6 (19.41)	-31.85 (1.51)		122 -40.1 (18.26)	-40.06 (1.51)	-8.20 (-12.4, -4.01) <.001 [-0.44 (-0.69, -0.18)]
Week 14		120 35.6 (18.61)			121 27.6 (17.26)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2177
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.407.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	120	-35.1 (19.93)	-34.55 (1.52)	121	-42.6 (19.45)	-42.01 (1.51)	-7.46 (-11.7, -3.25) <.001 [-0.38 (-0.63, -0.12)]
Week 16	118	36.0 (17.61)		117	26.5 (16.64)		
Week 16 chg	118	-35.0 (19.51)	-34.14 (1.52)	117	-43.9 (19.01)	-43.06 (1.52)	-8.92 (-13.1, -4.69) <.001 [-0.46 (-0.72, -0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2177
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.407.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 72.3 (14.77)		6	6 68.4 (12.78)		
Week 2		6 55.9 (21.25)			6 58.2 (18.23)		
Week 2 chg		6 -16.5 (14.63)	-11.29 (9.32)		6 -10.2 (15.55)	-15.43 (9.33)	-4.15 (-34.4, 26.15) 0.769 [-0.27 (-1.41, 0.86)]
Week 4		6 46.4 (24.47)			6 51.4 (15.24)		
Week 4 chg		6 -26.0 (24.11)	-19.88 (9.32)		6 -17.0 (16.91)	-23.20 (9.33)	-3.32 (-33.6, 26.98) 0.814 [-0.16 (-1.29, 0.97)]
Week 6		6 46.3 (29.64)			6 39.1 (17.55)		
Week 6 chg		6 -26.0 (23.86)	-20.62 (9.32)		6 -29.3 (19.46)	-34.77 (9.33)	-14.15 (-44.4, 16.14) 0.325 [-0.65 (-1.81, 0.51)]
Week 8		6 48.4 (34.74)			6 47.6 (19.36)		
Week 8 chg		6 -23.9 (29.39)	-18.32 (9.32)		6 -20.8 (23.74)	-26.48 (9.33)	-8.15 (-38.4, 22.14) 0.565 [-0.31 (-1.44, 0.83)]
Week 10		6 44.4 (31.54)			6 51.2 (21.84)		
Week 10 chg		6 -27.9 (26.21)	-22.14 (9.32)		6 -17.2 (26.15)	-23.03 (9.33)	-0.89 (-31.2, 29.40) 0.949 [-0.03 (-1.17, 1.10)]
Week 12		5 44.1 (35.13)			6 41.2 (23.80)		
Week 12 chg		5 -29.7 (27.31)	-20.13 (9.63)		6 -27.2 (25.77)	-32.69 (9.33)	-12.56 (-43.2, 18.03) 0.387 [-0.47 (-1.68, 0.73)]
Week 14		6 45.0 (35.62)			6 42.9 (25.09)		

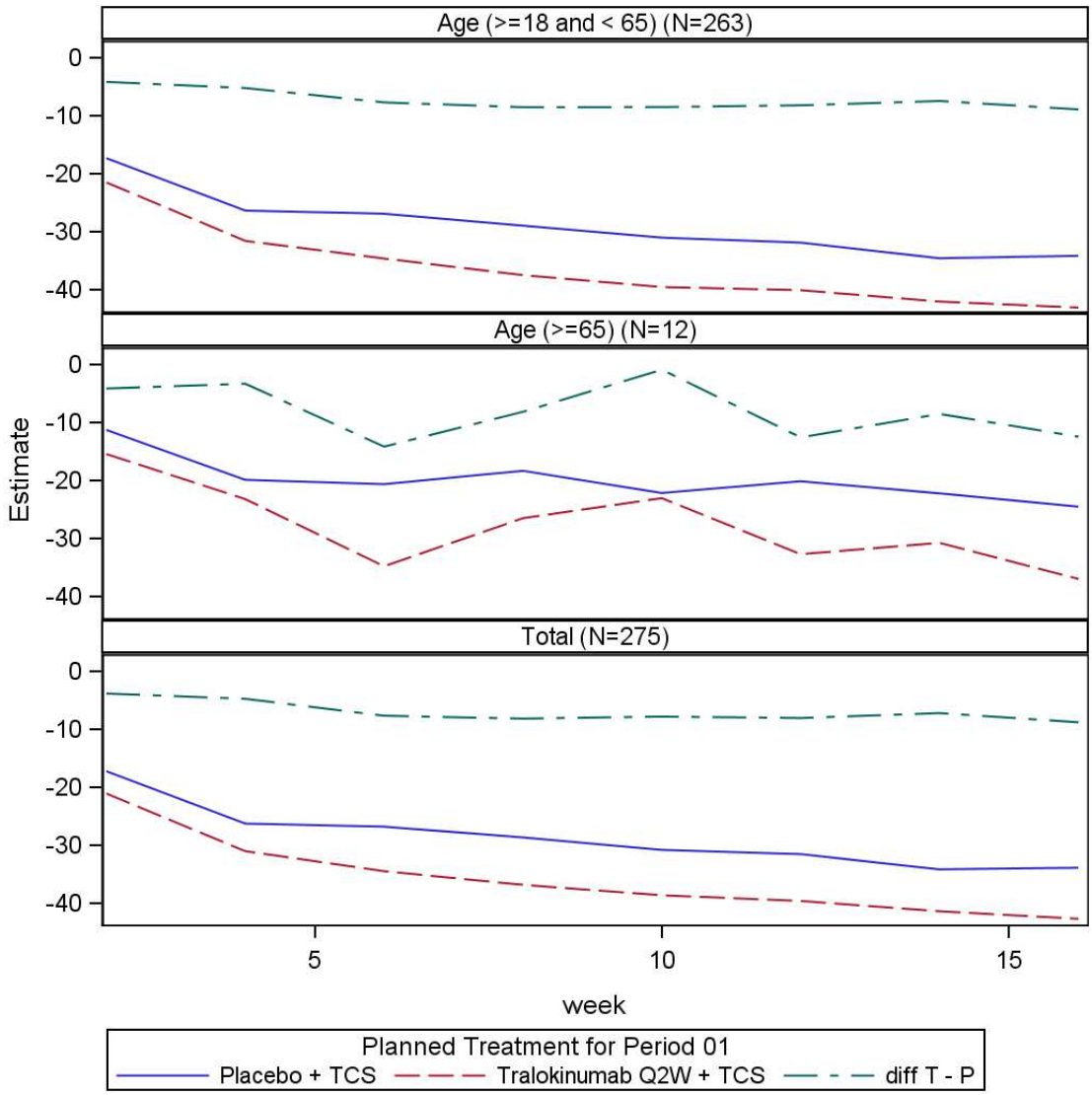
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2177
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.407.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	6	-27.4 (28.07)	-22.21 (9.32)	6	-25.5 (27.96)	-30.73 (9.33)	-8.53 (-38.8, 21.77) [-0.30 (-1.44, 0.83)]	0.548
Week 16	6	42.5 (36.99)		6	36.8 (20.60)			
Week 16 chg	6	-29.8 (28.96)	-24.50 (9.32)	6	-31.6 (26.11)	-36.95 (9.33)	-12.45 (-42.7, 17.85) [-0.45 (-1.60, 0.69)]	0.385

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2177
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.407.4.2: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.3.409.4.1: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score									
Total									
Baseline	137	134	16.4 (6.33)		138	137	15.9 (6.53)		
Week 2		131	9.2 (6.47)			132	8.5 (6.17)		
Week 2 chg		131	-7.2 (5.73)	-7.15 (0.45)		132	-7.5 (5.92)	-7.56 (0.45)	-0.41 (-1.65, 0.84) 0.520 [-0.07 (-0.31, 0.17)]
Week 4		130	7.8 (6.27)			135	6.7 (5.98)		
Week 4 chg		130	-8.6 (6.67)	-8.32 (0.45)		135	-9.0 (6.32)	-9.14 (0.44)	-0.82 (-2.06, 0.42) 0.196 [-0.13 (-0.37, 0.12)]
Week 6		123	7.3 (6.07)			126	6.0 (5.79)		
Week 6 chg		123	-8.9 (7.23)	-8.65 (0.45)		126	-10.0 (6.75)	-9.87 (0.45)	-1.22 (-2.48, 0.03) 0.056 [-0.18 (-0.42, 0.07)]
Week 8		127	6.9 (5.70)			128	5.4 (5.11)		
Week 8 chg		127	-9.4 (6.84)	-8.97 (0.45)		128	-10.6 (6.29)	-10.39 (0.45)	-1.42 (-2.67, -0.17) 0.026 [-0.22 (-0.46, 0.03)]
Week 12		123	6.8 (5.89)			124	5.0 (3.92)		
Week 12 chg		123	-9.8 (7.26)	-9.30 (0.46)		124	-10.6 (5.77)	-10.58 (0.45)	-1.28 (-2.54, -0.02) 0.046 [-0.20 (-0.45, 0.05)]
Week 16		120	6.5 (5.63)			118	4.5 (3.88)		
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.46)		118	-11.0 (5.99)	-11.18 (0.46)	-1.50 (-2.77, -0.23) 0.021 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3052
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.409.4.1: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	128 16.5 (6.34)		132	131 16.0 (6.43)		
Week 2		125 9.4 (6.53)			126 8.4 (6.28)		
Week 2 chg		125 -7.2 (5.75)	-7.10 (0.46)		126 -7.8 (5.74)	-7.79 (0.46)	-0.69 (-1.97, 0.59) 0.289 [-0.12 (-0.37, 0.13)]
Week 4		124 7.8 (6.36)			129 6.8 (6.07)		
Week 4 chg		124 -8.7 (6.74)	-8.45 (0.46)		129 -9.2 (6.20)	-9.25 (0.46)	-0.80 (-2.08, 0.47) 0.216 [-0.12 (-0.37, 0.12)]
Week 6		117 7.4 (6.04)			121 6.0 (5.90)		
Week 6 chg		117 -9.0 (7.38)	-8.70 (0.47)		121 -10.0 (6.77)	-9.99 (0.46)	-1.29 (-2.58, 0.00) 0.050 [-0.18 (-0.44, 0.07)]
Week 8		121 7.0 (5.77)			122 5.4 (5.21)		
Week 8 chg		121 -9.4 (6.94)	-9.00 (0.47)		122 -10.8 (6.11)	-10.58 (0.46)	-1.58 (-2.87, -0.29) 0.016 [-0.24 (-0.49, 0.01)]
Week 12		118 6.9 (5.95)			118 4.9 (3.96)		
Week 12 chg		118 -9.8 (7.38)	-9.34 (0.47)		118 -10.9 (5.51)	-10.81 (0.46)	-1.47 (-2.77, -0.18) 0.026 [-0.23 (-0.48, 0.03)]
Week 16		114 6.5 (5.59)			112 4.3 (3.81)		
Week 16 chg		114 -10.1 (6.64)	-9.78 (0.47)		112 -11.3 (5.68)	-11.45 (0.47)	-1.67 (-2.98, -0.37) 0.012 [-0.27 (-0.53, -0.01)]

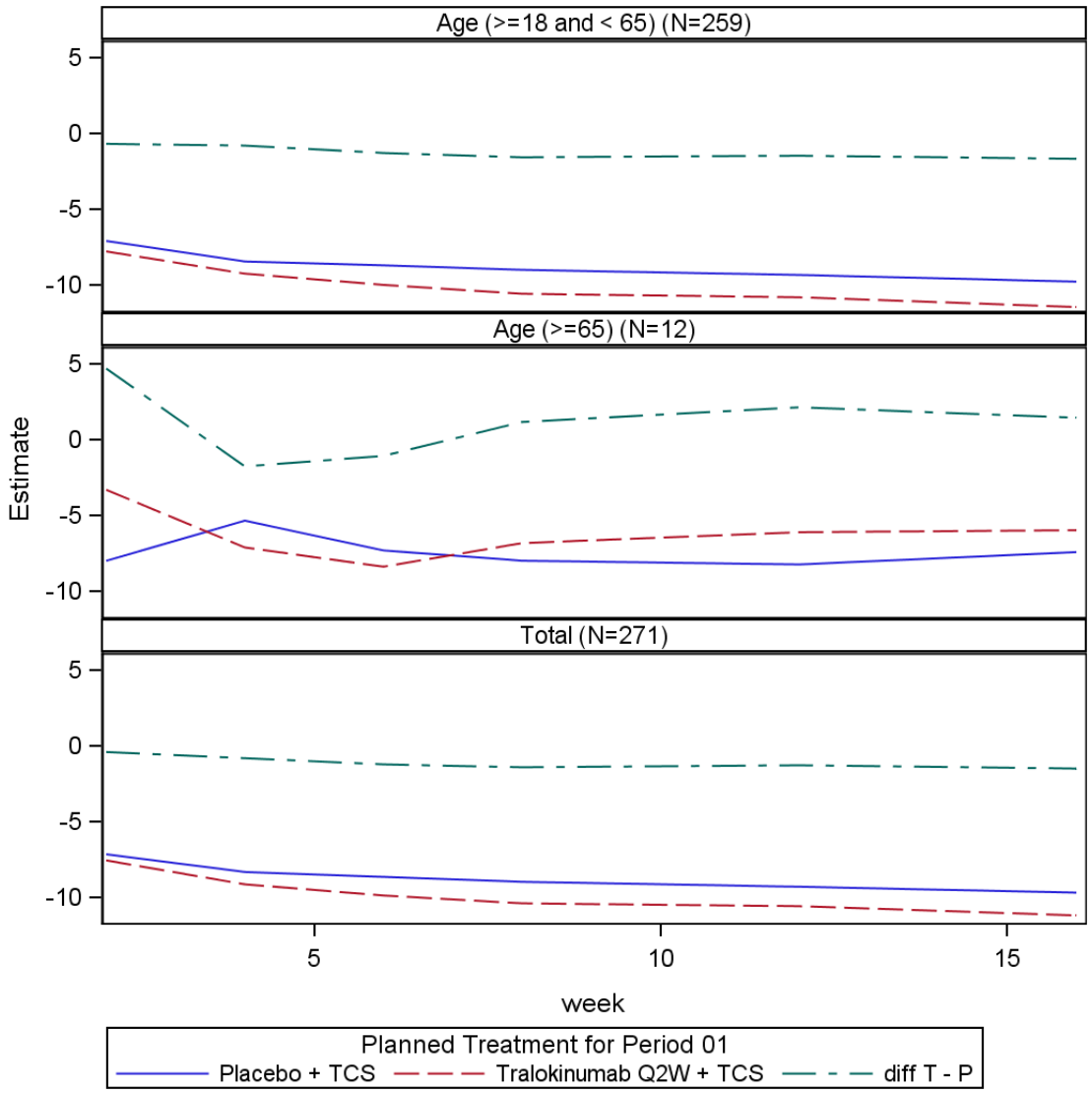
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3052
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.409.4.1: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 13.7 (6.09)		6	6 12.3 (8.38)		
Week 2		6 5.0 (3.16)			6 10.0 (2.97)		
Week 2 chg		6 -8.7 (5.47)	-8.00 (1.43)		6 -2.3 (7.76)	-3.31 (1.44)	4.69 (0.14, 9.24) 0.044 [0.70 (-0.47, 1.86)]
Week 4		6 7.7 (4.37)			6 6.2 (4.07)		
Week 4 chg		6 -6.0 (4.90)	-5.35 (1.43)		6 -6.2 (8.75)	-7.12 (1.44)	-1.77 (-6.32, 2.78) 0.415 [-0.25 (-1.39, 0.89)]
Week 6		6 5.8 (7.08)			5 5.4 (1.95)		
Week 6 chg		6 -7.8 (3.25)	-7.31 (1.43)		5 -9.2 (6.76)	-8.38 (1.50)	-1.07 (-5.67, 3.52) 0.623 [-0.21 (-1.40, 0.98)]
Week 8		6 5.0 (4.10)			6 6.5 (2.26)		
Week 8 chg		6 -8.7 (4.72)	-7.99 (1.43)		6 -5.8 (8.70)	-6.83 (1.44)	1.16 (-3.39, 5.71) 0.590 [0.17 (-0.97, 1.30)]
Week 12		5 4.6 (4.39)			6 7.2 (2.32)		
Week 12 chg		5 -9.6 (3.51)	-8.24 (1.49)		6 -5.2 (8.42)	-6.11 (1.44)	2.13 (-2.50, 6.76) 0.340 [0.32 (-0.88, 1.51)]
Week 16		6 5.7 (6.86)			6 7.2 (4.45)		
Week 16 chg		6 -8.0 (4.05)	-7.42 (1.43)		6 -5.2 (9.02)	-5.98 (1.44)	1.44 (-3.11, 5.99) 0.505 [0.21 (-0.93, 1.34)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3052
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.409.4.2: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.3.410.4.1: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total							
Total							
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)		
Week 2		130 15.1 (6.91)			130 13.5 (6.31)		
Week 2 chg		130 -5.9 (6.29)	-5.98 (0.55)		130 -7.7 (5.43)	-7.66 (0.54)	-1.69 (-3.20, -0.17) 0.029 [-0.29 (-0.53, -0.04)]
Week 4		130 13.8 (7.45)			133 11.6 (6.30)		
Week 4 chg		130 -7.1 (7.56)	-7.12 (0.55)		133 -9.7 (6.02)	-9.53 (0.54)	-2.40 (-3.92, -0.89) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123 13.5 (7.81)			124 10.9 (5.95)		
Week 6 chg		123 -7.2 (8.29)	-7.34 (0.55)		124 -10.6 (6.27)	-10.36 (0.55)	-3.02 (-4.56, -1.48) <.001 [-0.41 (-0.66, -0.16)]
Week 8		127 13.1 (7.02)			126 9.9 (5.79)		
Week 8 chg		127 -7.6 (7.95)	-7.73 (0.55)		126 -11.5 (6.10)	-11.20 (0.55)	-3.47 (-5.00, -1.94) <.001 [-0.49 (-0.74, -0.24)]
Week 12		123 13.0 (7.39)			122 9.2 (5.72)		
Week 12 chg		123 -8.0 (8.26)	-7.90 (0.55)		122 -12.4 (6.20)	-11.83 (0.55)	-3.93 (-5.47, -2.39) <.001 [-0.54 (-0.79, -0.28)]
Week 16		120 13.0 (7.69)			116 9.1 (5.58)		
Week 16 chg		120 -8.0 (8.09)	-8.05 (0.56)		116 -12.2 (6.39)	-11.87 (0.56)	-3.82 (-5.37, -2.27) <.001 [-0.52 (-0.78, -0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5644
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.410.4.1: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	128 20.9 (5.77)		132	129 21.3 (5.23)		
Week 2		124 15.2 (6.91)			124 13.4 (6.39)		
Week 2 chg		124 -5.9 (6.34)	-5.93 (0.56)		124 -7.9 (5.44)	-7.83 (0.55)	-1.90 (-3.44, -0.36) 0.016 [-0.32 (-0.57, -0.07)]
Week 4		124 13.7 (7.44)			127 11.4 (6.23)		
Week 4 chg		124 -7.2 (7.63)	-7.20 (0.56)		127 -9.9 (5.86)	-9.78 (0.55)	-2.58 (-4.12, -1.04) 0.001 [-0.38 (-0.63, -0.13)]
Week 6		117 13.6 (7.73)			119 10.7 (5.96)		
Week 6 chg		117 -7.2 (8.36)	-7.35 (0.56)		119 -10.8 (6.27)	-10.55 (0.56)	-3.20 (-4.76, -1.64) <.001 [-0.43 (-0.69, -0.18)]
Week 8		121 13.1 (6.87)			120 9.6 (5.76)		
Week 8 chg		121 -7.6 (8.02)	-7.75 (0.56)		120 -11.8 (6.02)	-11.47 (0.56)	-3.73 (-5.28, -2.17) <.001 [-0.52 (-0.78, -0.27)]
Week 12		118 13.3 (7.32)			116 9.0 (5.69)		
Week 12 chg		118 -7.8 (8.37)	-7.78 (0.56)		116 -12.6 (6.13)	-12.04 (0.56)	-4.26 (-5.83, -2.70) <.001 [-0.58 (-0.84, -0.32)]
Week 16		114 13.1 (7.59)			110 8.8 (5.43)		
Week 16 chg		114 -8.0 (8.19)	-7.97 (0.57)		110 -12.4 (6.27)	-12.08 (0.57)	-4.10 (-5.68, -2.53) <.001 [-0.56 (-0.83, -0.29)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5644
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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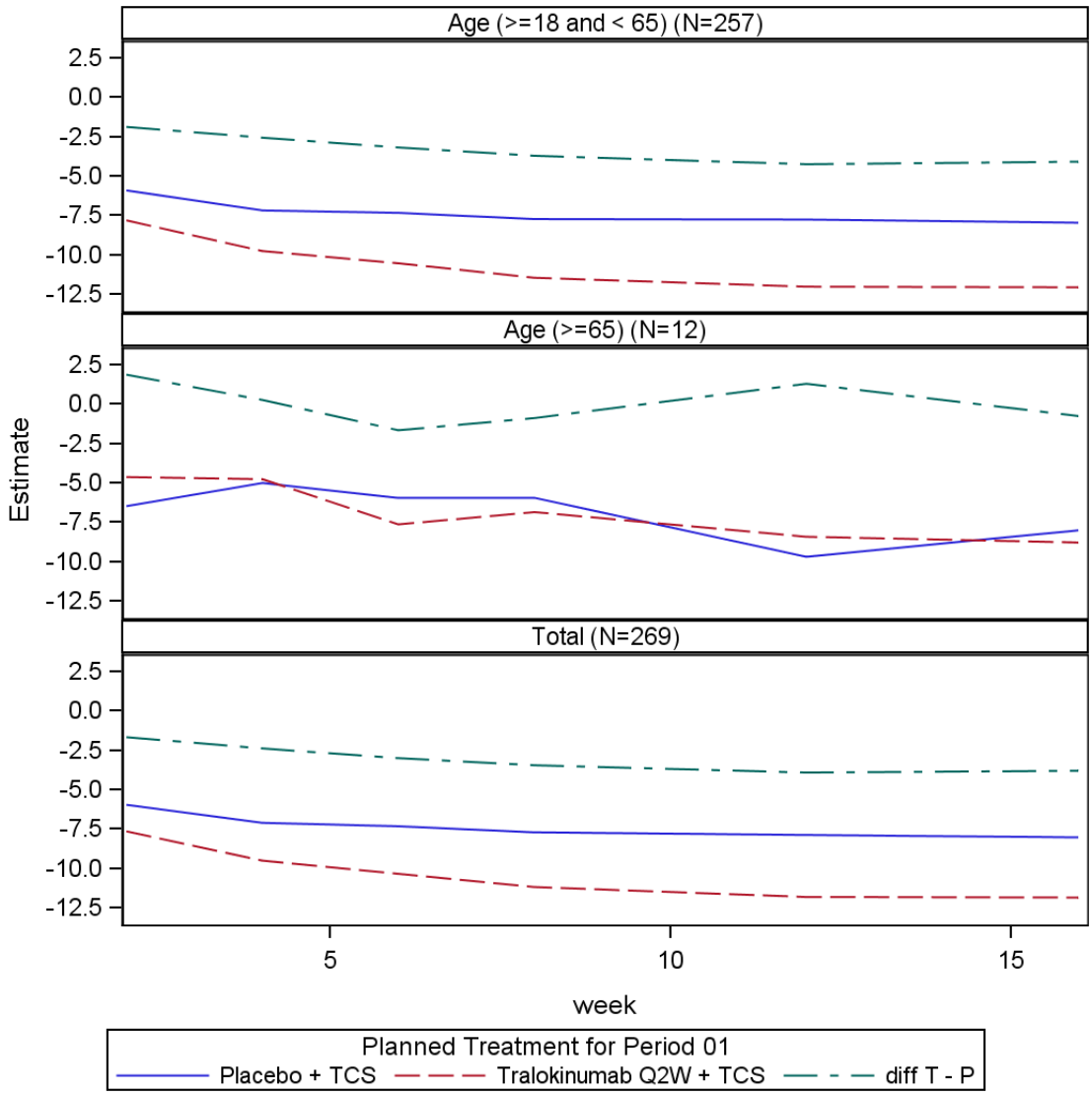
Table 1.3.410.4.1: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 19.3 (4.59)		6	6 21.3 (1.86)		
Week 2		6 12.7 (7.03)			6 16.8 (3.37)		
Week 2 chg		6 -6.7 (5.54)	-6.50 (2.86)		6 -4.5 (4.23)	-4.65 (2.87)	1.85 (-7.08, 10.79) 0.665 [0.38 (-0.77, 1.52)]
Week 4		6 14.2 (8.47)			6 16.7 (6.15)		
Week 4 chg		6 -5.2 (6.11)	-5.03 (2.86)		6 -4.7 (7.84)	-4.78 (2.87)	0.25 (-8.69, 9.18) 0.954 [0.03 (-1.10, 1.17)]
Week 6		6 12.7 (9.99)			5 14.4 (4.98)		
Week 6 chg		6 -6.7 (7.28)	-5.97 (2.86)		5 -7.2 (5.89)	-7.65 (3.02)	-1.68 (-10.8, 7.43) 0.701 [-0.25 (-1.44, 0.94)]
Week 8		6 12.5 (10.48)			6 15.3 (3.61)		
Week 8 chg		6 -6.8 (6.82)	-5.97 (2.86)		6 -6.0 (5.40)	-6.87 (2.87)	-0.90 (-9.84, 8.03) 0.832 [-0.15 (-1.28, 0.99)]
Week 12		5 7.0 (7.11)			6 13.3 (5.09)		
Week 12 chg		5 -11.8 (3.56)	-9.71 (3.05)		6 -8.0 (6.48)	-8.44 (2.87)	1.27 (-7.91, 10.46) 0.773 [0.24 (-0.95, 1.43)]
Week 16		6 10.5 (9.91)			6 13.3 (6.98)		
Week 16 chg		6 -8.8 (6.49)	-8.03 (2.86)		6 -8.0 (7.80)	-8.81 (2.87)	-0.77 (-9.71, 8.16) 0.856 [-0.11 (-1.24, 1.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5644
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.410.4.2: Total, Age group, change in POEM, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.3.414.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.60 (0.81)		138 -12.9 (10.72)	-13.33 (0.81)	-0.73 (-2.98, 1.53) 0.526 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.57 (0.81)		137 -18.8 (10.58)	-19.44 (0.81)	-1.86 (-4.13, 0.40) 0.106 [-0.17 (-0.40, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.53 (0.82)		134 -20.9 (11.93)	-21.51 (0.81)	-2.98 (-5.25, -0.71) 0.010 [-0.24 (-0.48, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.30 (0.82)		130 -22.5 (12.16)	-23.17 (0.82)	-3.88 (-6.15, -1.60) <.001 [-0.30 (-0.54, -0.05)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.61 (0.82)		130 -24.3 (11.55)	-25.02 (0.82)	-4.41 (-6.69, -2.13) <.001 [-0.34 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-21.10 (0.82)		128 -24.7 (12.40)	-25.22 (0.82)	-4.11 (-6.40, -1.83) <.001 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0164
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.414.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	11.2 (11.57)		127	7.0 (8.34)		
Week 14 chg	126	-22.8 (14.69)	-21.89 (0.82)	127	-25.1 (13.29)	-25.74 (0.82)	-3.85 (-6.14, -1.55) 0.001 [-0.27 (-0.52, -0.03)]
Week 16	124	10.5 (11.42)		123	6.4 (7.63)		
Week 16 chg	124	-23.8 (14.93)	-22.65 (0.83)	123	-25.9 (12.78)	-26.17 (0.83)	-3.52 (-5.82, -1.22) 0.003 [-0.25 (-0.50, -0.00)]
Week 18	116	10.7 (11.52)		115	5.9 (7.36)		
Week 18 chg	116	-23.6 (14.71)	-22.56 (0.84)	115	-26.4 (12.11)	-26.14 (0.84)	-3.58 (-5.91, -1.25) 0.003 [-0.27 (-0.52, -0.01)]
Week 20	107	10.6 (12.56)		117	5.5 (6.56)		
Week 20 chg	107	-24.1 (15.32)	-22.56 (0.85)	117	-26.9 (11.94)	-26.74 (0.84)	-4.18 (-6.53, -1.84) <.001 [-0.31 (-0.57, -0.04)]
Week 22	112	10.5 (11.17)		114	5.0 (5.93)		
Week 22 chg	112	-24.3 (14.63)	-22.40 (0.84)	114	-27.3 (12.17)	-27.13 (0.84)	-4.73 (-7.08, -2.39) <.001 [-0.35 (-0.61, -0.09)]
Week 24	112	9.9 (11.00)		117	5.3 (7.21)		
Week 24 chg	112	-24.9 (14.38)	-22.80 (0.84)	117	-27.0 (12.11)	-26.99 (0.84)	-4.19 (-6.53, -1.85) <.001 [-0.32 (-0.58, -0.06)]
Week 26	118	9.1 (10.14)		125	5.6 (7.90)		
Week 26 chg	118	-25.5 (13.74)	-23.71 (0.83)	125	-26.5 (12.83)	-27.01 (0.82)	-3.30 (-5.61, -0.99) 0.005 [-0.25 (-0.50, 0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0164
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.3.414.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	131 33.8 (13.62)		132	132 31.9 (11.55)		
Week 2		131 20.9 (14.06)			132 18.9 (12.71)		
Week 2 chg		131 -12.9 (11.34)	-12.62 (0.79)		132 -13.0 (10.84)	-13.50 (0.79)	-0.88 (-3.09, 1.33) 0.433 [-0.08 (-0.32, 0.16)]
Week 4		128 15.6 (12.55)			131 12.8 (10.30)		
Week 4 chg		128 -18.3 (11.99)	-17.61 (0.80)		131 -19.0 (10.42)	-19.58 (0.79)	-1.97 (-4.19, 0.25) 0.081 [-0.18 (-0.42, 0.07)]
Week 6		126 14.7 (12.29)			128 10.8 (9.31)		
Week 6 chg		126 -19.3 (12.73)	-18.54 (0.80)		128 -21.1 (11.57)	-21.72 (0.80)	-3.17 (-5.40, -0.95) 0.005 [-0.26 (-0.51, -0.01)]
Week 8		127 13.8 (12.56)			124 9.2 (8.10)		
Week 8 chg		127 -20.1 (13.86)	-19.42 (0.80)		124 -22.8 (11.86)	-23.43 (0.80)	-4.01 (-6.24, -1.78) <.001 [-0.31 (-0.56, -0.06)]
Week 10		125 12.3 (11.42)			124 7.3 (7.20)		
Week 10 chg		125 -21.7 (13.91)	-20.79 (0.80)		124 -24.5 (11.41)	-25.23 (0.80)	-4.45 (-6.68, -2.21) <.001 [-0.35 (-0.60, -0.10)]
Week 12		123 11.8 (10.86)			122 7.4 (7.46)		
Week 12 chg		123 -22.4 (14.22)	-21.32 (0.81)		122 -24.8 (12.03)	-25.29 (0.81)	-3.97 (-6.21, -1.73) <.001 [-0.30 (-0.55, -0.05)]
Week 14		120 10.8 (10.68)			121 6.6 (7.73)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0164
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.414.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	120	-23.2 (14.41)	-22.27 (0.81)	121	-25.4 (12.82)	-25.96 (0.81)	-3.69 (-5.94, -1.44) 0.001 [-0.27 (-0.52, -0.02)]
Week 16	118	10.1 (10.37)		117	6.1 (7.17)		
Week 16 chg	118	-24.2 (14.61)	-23.04 (0.81)	117	-26.0 (12.32)	-26.28 (0.81)	-3.24 (-5.50, -0.98) 0.005 [-0.24 (-0.50, 0.02)]
Week 18	110	10.2 (10.43)		110	5.6 (6.93)		
Week 18 chg	110	-24.1 (14.35)	-22.96 (0.82)	110	-26.4 (11.87)	-26.43 (0.82)	-3.46 (-5.76, -1.17) 0.003 [-0.26 (-0.53, 0.00)]
Week 20	102	10.0 (11.32)		112	5.5 (6.54)		
Week 20 chg	102	-24.6 (14.92)	-23.03 (0.84)	112	-26.8 (11.75)	-26.84 (0.82)	-3.80 (-6.11, -1.50) 0.001 [-0.28 (-0.55, -0.02)]
Week 22	108	10.6 (11.01)		109	4.9 (5.86)		
Week 22 chg	108	-24.2 (14.83)	-22.57 (0.83)	109	-27.2 (12.02)	-27.23 (0.82)	-4.65 (-6.95, -2.35) <.001 [-0.34 (-0.61, -0.08)]
Week 24	108	10.0 (11.00)		112	5.3 (7.22)		
Week 24 chg	108	-24.7 (14.60)	-22.91 (0.83)	112	-26.8 (11.93)	-27.04 (0.82)	-4.13 (-6.42, -1.84) <.001 [-0.31 (-0.58, -0.04)]
Week 26	114	9.2 (10.12)		119	5.3 (7.08)		
Week 26 chg	114	-25.4 (13.94)	-23.83 (0.82)	119	-26.7 (12.10)	-27.17 (0.81)	-3.34 (-5.61, -1.08) 0.004 [-0.26 (-0.51, 0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0164
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.3.414.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 34.8 (10.31)		6	6 35.5 (11.49)		
Week 2		6 22.3 (12.01)			6 26.4 (12.49)		
Week 2 chg		6 -12.5 (6.88)	-9.27 (5.75)		6 -9.1 (6.97)	-12.43 (5.75)	-3.16 (-21.5, 15.15) 0.712 [-0.46 (-1.60, 0.69)]
Week 4		6 17.8 (14.32)			6 20.0 (10.39)		
Week 4 chg		6 -17.0 (11.46)	-14.14 (5.75)		6 -15.5 (14.37)	-18.86 (5.75)	-4.72 (-23.0, 13.59) 0.583 [-0.36 (-1.50, 0.78)]
Week 6		6 16.5 (15.78)			6 19.1 (14.42)		
Week 6 chg		6 -18.3 (11.07)	-15.44 (5.75)		6 -16.4 (19.04)	-19.71 (5.75)	-4.27 (-22.6, 14.04) 0.619 [-0.27 (-1.41, 0.86)]
Week 8		6 18.0 (16.71)			6 18.4 (12.22)		
Week 8 chg		6 -16.8 (14.37)	-14.01 (5.75)		6 -17.2 (17.96)	-20.49 (5.75)	-6.48 (-24.8, 11.83) 0.454 [-0.40 (-1.54, 0.74)]
Week 10		6 17.8 (16.39)			6 15.6 (8.36)		
Week 10 chg		6 -16.9 (15.00)	-14.19 (5.75)		6 -19.9 (14.67)	-23.24 (5.75)	-9.05 (-27.4, 9.25) 0.301 [-0.61 (-1.77, 0.55)]
Week 12		5 18.2 (18.47)			6 12.7 (13.60)		
Week 12 chg		5 -17.9 (16.36)	-13.44 (5.92)		6 -22.9 (19.87)	-26.18 (5.75)	-12.74 (-31.2, 5.72) 0.159 [-0.69 (-1.91, 0.53)]
Week 14		6 20.6 (22.81)			6 14.9 (15.50)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0164
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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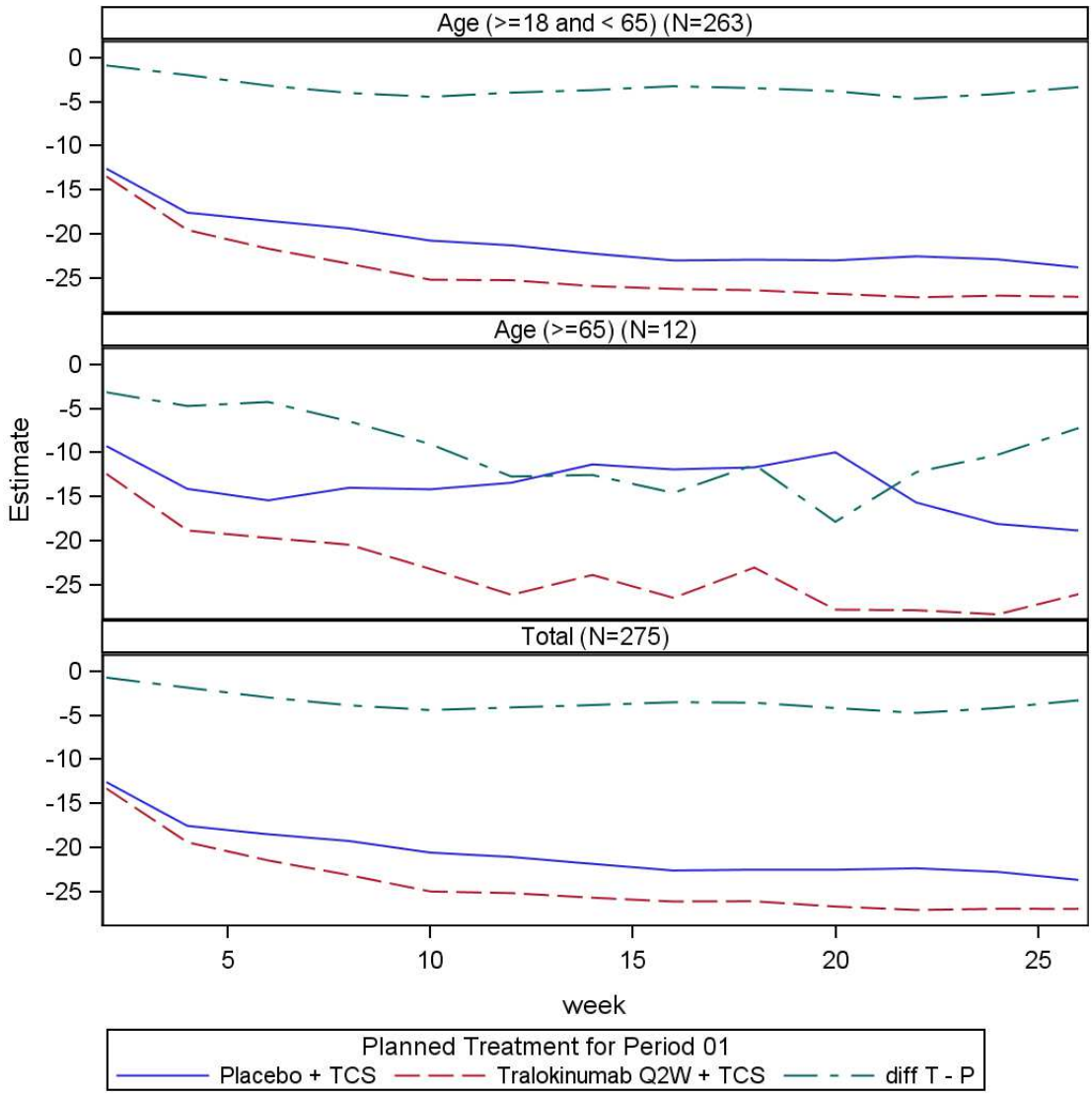
Table 1.3.414.4.1: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg		6 -14.2 (18.93)	-11.36 (5.75)		6 -20.6 (21.84)	-23.92 (5.75)	-12.56 (-30.9, 5.75) 0.160 [-0.61 (-1.77, 0.54)]
Week 16		6 20.0 (24.05)			6 12.3 (13.57)		
Week 16 chg		6 -14.7 (19.67)	-11.93 (5.75)		6 -23.2 (21.25)	-26.52 (5.75)	-14.59 (-32.9, 3.72) 0.107 [-0.71 (-1.88, 0.45)]
Week 18		6 20.2 (23.83)			5 11.9 (13.57)		
Week 18 chg		6 -14.6 (19.70)	-11.69 (5.75)		5 -24.9 (18.31)	-23.08 (5.92)	-11.39 (-29.8, 7.06) 0.203 [-0.60 (-1.81, 0.62)]
Week 20		5 21.9 (27.96)			5 7.1 (7.68)		
Week 20 chg		5 -14.3 (21.76)	-9.98 (5.92)		5 -29.8 (17.17)	-27.86 (5.92)	-17.88 (-36.5, 0.71) 0.058 [-0.91 (-2.21, 0.39)]
Week 22		4 9.4 (16.87)			5 6.8 (7.93)		
Week 22 chg		4 -25.7 (8.76)	-15.70 (6.15)		5 -30.0 (16.59)	-27.93 (5.92)	-12.23 (-31.1, 6.59) 0.185 [-0.89 (-2.26, 0.49)]
Week 24		4 7.0 (12.30)			5 6.1 (7.84)		
Week 24 chg		4 -28.1 (6.35)	-18.13 (6.15)		5 -30.7 (16.97)	-28.40 (5.92)	-10.28 (-29.1, 8.55) 0.260 [-0.76 (-2.12, 0.60)]
Week 26		4 6.3 (11.87)			6 12.7 (17.45)		
Week 26 chg		4 -28.8 (5.94)	-18.87 (6.16)		6 -22.8 (24.64)	-26.11 (5.75)	-7.24 (-25.9, 11.44) 0.417 [-0.37 (-1.64, 0.91)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0164
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.414.4.2: Total, Age group, change in EASI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)									
Total									
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)		
Week 1		135	6.3 (1.69)			136	6.0 (1.78)		
Week 1 chg		135	-1.1 (1.34)	-1.12 (0.18)		136	-1.2 (1.31)	-1.22 (0.18)	-0.10 (-0.60, 0.40) 0.699 [-0.07 (-0.31, 0.16)]
Week 2		134	5.8 (1.97)			132	5.4 (2.11)		
Week 2 chg		134	-1.7 (1.78)	-1.67 (0.18)		132	-1.9 (1.67)	-1.92 (0.18)	-0.24 (-0.74, 0.26) 0.338 [-0.14 (-0.38, 0.10)]
Week 3		133	5.3 (2.17)			131	4.8 (2.08)		
Week 3 chg		133	-2.2 (2.12)	-2.11 (0.18)		131	-2.5 (1.84)	-2.53 (0.18)	-0.42 (-0.92, 0.08) 0.097 [-0.21 (-0.46, 0.03)]
Week 4		130	5.1 (2.25)			133	4.4 (2.14)		
Week 4 chg		130	-2.4 (2.14)	-2.29 (0.18)		133	-2.8 (1.92)	-2.87 (0.18)	-0.58 (-1.08, -0.08) 0.023 [-0.29 (-0.53, -0.04)]
Week 5		131	4.9 (2.37)			129	4.2 (2.15)		
Week 5 chg		131	-2.6 (2.26)	-2.53 (0.18)		129	-3.1 (1.92)	-3.16 (0.18)	-0.63 (-1.13, -0.13) 0.014 [-0.30 (-0.54, -0.06)]
Week 6		130	4.8 (2.35)			129	4.2 (2.16)		
Week 6 chg		130	-2.7 (2.25)	-2.55 (0.18)		129	-3.1 (1.99)	-3.15 (0.18)	-0.61 (-1.11, -0.10) 0.018 [-0.29 (-0.53, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	4.7 (2.24)		128	4.0 (2.13)			
Week 7 chg	129	-2.8 (2.25)	-2.69 (0.18)	128	-3.3 (2.05)	-3.38 (0.18)	-0.69 (-1.19, -0.19) [-0.32 (-0.57, -0.07)]	0.007
Week 8	127	4.7 (2.32)		125	3.7 (2.10)			
Week 8 chg	127	-2.8 (2.27)	-2.69 (0.18)	125	-3.7 (1.96)	-3.65 (0.18)	-0.96 (-1.46, -0.46) [-0.45 (-0.70, -0.20)]	<.001
Week 9	127	4.6 (2.37)		127	3.6 (2.10)			
Week 9 chg	127	-2.9 (2.32)	-2.76 (0.18)	127	-3.7 (2.03)	-3.71 (0.18)	-0.95 (-1.45, -0.45) [-0.44 (-0.69, -0.19)]	<.001
Week 10	125	4.5 (2.42)		122	3.6 (2.11)			
Week 10 chg	125	-2.9 (2.39)	-2.84 (0.18)	122	-3.7 (1.93)	-3.70 (0.18)	-0.87 (-1.37, -0.36) [-0.40 (-0.65, -0.15)]	<.001
Week 11	128	4.4 (2.41)		126	3.5 (2.15)			
Week 11 chg	128	-3.1 (2.40)	-3.03 (0.18)	126	-3.7 (1.97)	-3.76 (0.18)	-0.73 (-1.23, -0.23) [-0.33 (-0.58, -0.09)]	0.004
Week 12	123	4.4 (2.36)		121	3.5 (2.08)			
Week 12 chg	123	-3.1 (2.41)	-2.99 (0.18)	121	-3.8 (2.06)	-3.82 (0.18)	-0.83 (-1.33, -0.32) [-0.37 (-0.62, -0.12)]	0.001
Week 13	116	4.3 (2.38)		120	3.3 (2.06)			
Week 13 chg	116	-3.3 (2.35)	-3.05 (0.18)	120	-4.0 (2.09)	-3.92 (0.18)	-0.87 (-1.38, -0.37) [-0.39 (-0.65, -0.14)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.11 (0.18)	123	-3.9 (2.12)	-3.85 (0.18)	-0.74 (-1.25, -0.24) [-0.33 (-0.59, -0.08)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.17 (0.18)	123	-4.0 (2.15)	-3.93 (0.18)	-0.76 (-1.26, -0.25) [-0.34 (-0.59, -0.09)]	0.003
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.09 (0.18)	122	-3.9 (2.06)	-3.95 (0.18)	-0.85 (-1.36, -0.35) [-0.39 (-0.64, -0.13)]	<.001
Week 17	121	4.3 (2.46)		121	3.4 (2.13)			
Week 17 chg	121	-3.2 (2.49)	-3.09 (0.18)	121	-3.9 (2.04)	-3.93 (0.18)	-0.84 (-1.35, -0.34) [-0.37 (-0.63, -0.12)]	0.001
Week 18	120	4.4 (2.51)		123	3.3 (2.12)			
Week 18 chg	120	-3.2 (2.46)	-3.04 (0.18)	123	-4.0 (2.11)	-3.96 (0.18)	-0.93 (-1.43, -0.42) [-0.40 (-0.66, -0.15)]	<.001
Week 19	119	4.3 (2.65)		117	3.1 (2.11)			
Week 19 chg	119	-3.3 (2.55)	-3.09 (0.18)	117	-4.2 (2.19)	-4.16 (0.18)	-1.07 (-1.58, -0.57) [-0.45 (-0.71, -0.19)]	<.001
Week 20	120	4.3 (2.68)		118	3.0 (2.02)			
Week 20 chg	120	-3.3 (2.61)	-3.08 (0.18)	118	-4.2 (2.13)	-4.13 (0.18)	-1.05 (-1.56, -0.54) [-0.44 (-0.70, -0.18)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21	118	4.2 (2.59)		115	3.0 (1.94)		
Week 21 chg	118	-3.4 (2.59)	-3.21 (0.18)	115	-4.3 (2.07)	-4.22 (0.18)	-1.01 (-1.52, -0.50) <.001 [-0.43 (-0.69, -0.17)]
Week 22	120	4.2 (2.64)		116	3.0 (1.90)		
Week 22 chg	120	-3.4 (2.64)	-3.23 (0.18)	116	-4.2 (2.06)	-4.23 (0.18)	-1.01 (-1.51, -0.50) <.001 [-0.42 (-0.68, -0.17)]
Week 23	120	4.1 (2.62)		114	3.0 (1.94)		
Week 23 chg	120	-3.5 (2.58)	-3.28 (0.18)	114	-4.3 (2.15)	-4.23 (0.18)	-0.95 (-1.46, -0.44) <.001 [-0.40 (-0.66, -0.14)]
Week 24	120	4.1 (2.52)		112	2.9 (1.92)		
Week 24 chg	120	-3.4 (2.53)	-3.26 (0.18)	112	-4.3 (2.13)	-4.28 (0.18)	-1.02 (-1.53, -0.51) <.001 [-0.43 (-0.69, -0.17)]
Week 25	114	3.8 (2.46)		115	2.9 (1.90)		
Week 25 chg	114	-3.8 (2.50)	-3.46 (0.18)	115	-4.3 (2.08)	-4.34 (0.18)	-0.88 (-1.39, -0.37) <.001 [-0.38 (-0.65, -0.12)]
Week 26	112	3.9 (2.49)		118	3.0 (1.91)		
Week 26 chg	112	-3.6 (2.56)	-3.32 (0.18)	118	-4.3 (2.11)	-4.28 (0.18)	-0.96 (-1.47, -0.45) <.001 [-0.41 (-0.67, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)											
Baseline	131	130	7.5 (1.34)			132	131	7.3 (1.40)			
Week 1		129	6.4 (1.69)				130	6.1 (1.75)			
Week 1 chg		129	-1.1 (1.37)	-1.12	(0.18)		130	-1.3 (1.29)	-1.26	(0.18)	-0.14 (-0.65, 0.36) 0.575 [-0.11 (-0.35, 0.14)]
Week 2		128	5.8 (1.96)				126	5.4 (2.12)			
Week 2 chg		128	-1.7 (1.81)	-1.66	(0.18)		126	-2.0 (1.66)	-1.99	(0.18)	-0.32 (-0.83, 0.18) 0.213 [-0.19 (-0.43, 0.06)]
Week 3		127	5.3 (2.17)				125	4.8 (2.08)			
Week 3 chg		127	-2.2 (2.15)	-2.11	(0.18)		125	-2.6 (1.82)	-2.61	(0.18)	-0.50 (-1.00, 0.01) 0.054 [-0.25 (-0.50, -0.00)]
Week 4		124	5.1 (2.23)				127	4.4 (2.13)			
Week 4 chg		124	-2.4 (2.16)	-2.34	(0.18)		127	-2.9 (1.90)	-2.95	(0.18)	-0.61 (-1.12, -0.11) 0.017 [-0.30 (-0.55, -0.05)]
Week 5		125	4.9 (2.36)				123	4.1 (2.15)			
Week 5 chg		125	-2.7 (2.29)	-2.57	(0.18)		123	-3.2 (1.88)	-3.26	(0.18)	-0.69 (-1.20, -0.18) 0.008 [-0.33 (-0.58, -0.08)]
Week 6		124	4.8 (2.33)				123	4.2 (2.15)			
Week 6 chg		124	-2.7 (2.27)	-2.59	(0.18)		123	-3.2 (1.98)	-3.24	(0.18)	-0.64 (-1.15, -0.14) 0.013 [-0.30 (-0.55, -0.05)]
Week 7		123	4.6 (2.22)				122	3.9 (2.12)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	123	-2.9 (2.26)	-2.74 (0.18)	122	-3.4 (2.03)	-3.48 (0.18)	-0.74 (-1.24, -0.23) [-0.34 (-0.60, -0.09)]	0.005
Week 8	121	4.7 (2.28)		119	3.6 (2.10)			
Week 8 chg	121	-2.9 (2.27)	-2.74 (0.18)	119	-3.8 (1.93)	-3.74 (0.18)	-1.00 (-1.51, -0.49) [-0.47 (-0.73, -0.22)]	<.001
Week 9	121	4.6 (2.35)		121	3.6 (2.09)			
Week 9 chg	121	-2.9 (2.34)	-2.80 (0.18)	121	-3.8 (1.97)	-3.82 (0.18)	-1.02 (-1.53, -0.51) [-0.47 (-0.73, -0.21)]	<.001
Week 10	119	4.5 (2.38)		116	3.6 (2.09)			
Week 10 chg	119	-3.0 (2.39)	-2.89 (0.18)	116	-3.8 (1.86)	-3.82 (0.18)	-0.93 (-1.44, -0.41) [-0.43 (-0.69, -0.17)]	<.001
Week 11	122	4.3 (2.37)		120	3.5 (2.13)			
Week 11 chg	122	-3.2 (2.41)	-3.09 (0.18)	120	-3.9 (1.91)	-3.87 (0.18)	-0.78 (-1.29, -0.28) [-0.36 (-0.61, -0.11)]	0.003
Week 12	118	4.4 (2.38)		115	3.5 (2.05)			
Week 12 chg	118	-3.1 (2.43)	-3.02 (0.18)	115	-3.9 (2.01)	-3.93 (0.18)	-0.92 (-1.43, -0.41) [-0.41 (-0.67, -0.15)]	<.001
Week 13	111	4.3 (2.38)		114	3.2 (2.04)			
Week 13 chg	111	-3.3 (2.36)	-3.10 (0.19)	114	-4.1 (2.04)	-4.03 (0.18)	-0.93 (-1.45, -0.42) [-0.42 (-0.69, -0.16)]	<.001
Week 14	118	4.3 (2.37)		118	3.3 (2.12)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	118	-3.3 (2.35)	-3.16 (0.18)	118	-4.0 (2.09)	-3.96 (0.18)	-0.81 (-1.32, -0.29) [-0.36 (-0.62, -0.10)]	0.002
Week 15	117	4.2 (2.30)		117	3.3 (2.11)			
Week 15 chg	117	-3.4 (2.34)	-3.22 (0.18)	117	-4.1 (2.09)	-4.04 (0.18)	-0.81 (-1.32, -0.30) [-0.37 (-0.62, -0.11)]	0.002
Week 16	115	4.2 (2.28)		116	3.3 (2.03)			
Week 16 chg	115	-3.4 (2.36)	-3.15 (0.18)	116	-4.1 (1.99)	-4.06 (0.18)	-0.91 (-1.42, -0.39) [-0.41 (-0.68, -0.15)]	<.001
Week 17	115	4.3 (2.44)		115	3.3 (2.10)			
Week 17 chg	115	-3.3 (2.51)	-3.13 (0.18)	115	-4.0 (1.95)	-4.06 (0.18)	-0.92 (-1.44, -0.41) [-0.41 (-0.67, -0.15)]	<.001
Week 18	114	4.4 (2.51)		117	3.2 (2.09)			
Week 18 chg	114	-3.2 (2.49)	-3.08 (0.18)	117	-4.1 (2.02)	-4.08 (0.18)	-1.00 (-1.51, -0.49) [-0.44 (-0.70, -0.18)]	<.001
Week 19	113	4.3 (2.63)		111	3.0 (2.10)			
Week 19 chg	113	-3.3 (2.58)	-3.11 (0.18)	111	-4.3 (2.11)	-4.28 (0.18)	-1.16 (-1.68, -0.65) [-0.49 (-0.76, -0.23)]	<.001
Week 20	114	4.3 (2.69)		112	2.9 (1.99)			
Week 20 chg	114	-3.3 (2.66)	-3.14 (0.18)	112	-4.4 (2.04)	-4.26 (0.18)	-1.12 (-1.63, -0.60) [-0.47 (-0.73, -0.21)]	<.001
Week 21	113	4.2 (2.61)		109	2.9 (1.87)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	113	-3.4 (2.63)	-3.26 (0.18)	109	-4.4 (1.93)	-4.37 (0.19)	-1.11 (-1.63, -0.60) <.001 [-0.48 (-0.75, -0.21)]
Week 22	115	4.2 (2.63)		110	2.9 (1.84)		
Week 22 chg	115	-3.4 (2.66)	-3.27 (0.18)	110	-4.4 (1.93)	-4.38 (0.19)	-1.11 (-1.62, -0.59) <.001 [-0.47 (-0.74, -0.21)]
Week 23	115	4.1 (2.61)		108	2.8 (1.84)		
Week 23 chg	115	-3.5 (2.61)	-3.31 (0.18)	108	-4.5 (1.96)	-4.40 (0.19)	-1.09 (-1.61, -0.58) <.001 [-0.47 (-0.74, -0.20)]
Week 24	115	4.1 (2.50)		106	2.8 (1.83)		
Week 24 chg	115	-3.5 (2.54)	-3.31 (0.18)	106	-4.5 (1.96)	-4.43 (0.19)	-1.12 (-1.63, -0.60) <.001 [-0.49 (-0.76, -0.22)]
Week 25	110	3.8 (2.47)		109	2.8 (1.82)		
Week 25 chg	110	-3.8 (2.52)	-3.49 (0.19)	109	-4.5 (1.99)	-4.47 (0.19)	-0.98 (-1.50, -0.46) <.001 [-0.43 (-0.70, -0.16)]
Week 26	108	4.0 (2.50)		112	2.9 (1.86)		
Week 26 chg	108	-3.6 (2.58)	-3.35 (0.19)	112	-4.4 (2.04)	-4.40 (0.18)	-1.05 (-1.57, -0.53) <.001 [-0.45 (-0.72, -0.18)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 7.2 (2.17)		6	6 5.8 (1.98)		
Week 1		6 5.8 (1.89)			6 5.5 (2.50)		
Week 1 chg		6 -1.4 (0.66)	-0.99 (0.88)		6 -0.3 (1.46)	-0.69 (0.85)	0.30 (-2.72, 3.32) 0.828 [0.26 (-0.87, 1.40)]
Week 2		6 5.2 (2.29)			6 5.5 (1.98)		
Week 2 chg		6 -2.0 (1.03)	-1.55 (0.88)		6 -0.3 (1.14)	-0.67 (0.85)	0.88 (-2.14, 3.90) 0.527 [0.81 (-0.37, 1.99)]
Week 3		6 4.8 (2.21)			6 5.0 (2.28)		
Week 3 chg		6 -2.4 (1.36)	-1.93 (0.88)		6 -0.8 (1.29)	-1.15 (0.85)	0.78 (-2.24, 3.80) 0.575 [0.59 (-0.57, 1.74)]
Week 4		6 5.7 (2.89)			6 4.8 (2.51)		
Week 4 chg		6 -1.4 (1.65)	-1.16 (0.88)		6 -1.0 (1.40)	-1.23 (0.85)	-0.07 (-3.09, 2.95) 0.959 [-0.05 (-1.18, 1.09)]
Week 5		6 5.2 (2.75)			6 4.9 (2.33)		
Week 5 chg		6 -2.0 (1.57)	-1.62 (0.88)		6 -0.9 (1.44)	-1.20 (0.85)	0.42 (-2.60, 3.43) 0.764 [0.28 (-0.86, 1.41)]
Week 6		6 5.3 (2.90)			6 4.6 (2.41)		
Week 6 chg		6 -1.9 (1.81)	-1.58 (0.88)		6 -1.2 (1.07)	-1.51 (0.85)	0.07 (-2.94, 3.09) 0.958 [0.05 (-1.08, 1.18)]
Week 7		6 5.1 (2.81)			6 4.6 (2.35)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	6	-2.1 (2.10)	-1.69 (0.88)	6	-1.2 (1.20)	-1.52 (0.85)	0.17 (-2.85, 3.19) [0.10 (-1.03, 1.23)]	0.902
Week 8	6	5.3 (3.23)		6	4.2 (2.23)			
Week 8 chg	6	-1.9 (2.23)	-1.61 (0.88)	6	-1.6 (1.08)	-1.85 (0.85)	-0.24 (-3.26, 2.77) [-0.14 (-1.27, 0.99)]	0.860
Week 9	6	5.0 (2.95)		6	4.5 (2.30)			
Week 9 chg	6	-2.2 (2.05)	-1.81 (0.88)	6	-1.3 (1.66)	-1.65 (0.85)	0.17 (-2.85, 3.18) [0.09 (-1.04, 1.22)]	0.903
Week 10	6	5.1 (3.33)		6	4.6 (2.44)			
Week 10 chg	6	-2.1 (2.23)	-1.74 (0.88)	6	-1.2 (1.73)	-1.48 (0.85)	0.26 (-2.76, 3.28) [0.13 (-1.00, 1.26)]	0.849
Week 11	6	5.1 (3.34)		6	4.6 (2.54)			
Week 11 chg	6	-2.1 (2.07)	-1.83 (0.88)	6	-1.2 (1.45)	-1.41 (0.85)	0.42 (-2.60, 3.44) [0.24 (-0.90, 1.37)]	0.760
Week 12	5	3.6 (2.02)		6	4.7 (2.55)			
Week 12 chg	5	-3.0 (2.09)	-2.42 (0.89)	6	-1.2 (1.38)	-1.50 (0.85)	0.92 (-2.10, 3.94) [0.53 (-0.68, 1.74)]	0.510
Week 13	5	4.2 (2.63)		6	4.5 (2.29)			
Week 13 chg	5	-2.5 (2.17)	-1.90 (0.89)	6	-1.4 (1.22)	-1.65 (0.85)	0.25 (-2.77, 3.27) [0.15 (-1.04, 1.33)]	0.857
Week 14	5	4.0 (2.93)		5	4.4 (2.50)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	5	-2.7 (2.02)	-2.13 (0.89)	5	-1.6 (1.37)	-1.71 (0.87)	0.42 (-2.61, 3.44) [0.24 (-1.00, 1.48)]	0.765
Week 15	6	4.6 (2.81)		6	4.4 (2.03)			
Week 15 chg	6	-2.5 (1.89)	-2.05 (0.88)	6	-1.4 (1.74)	-1.85 (0.85)	0.20 (-2.82, 3.21) [0.11 (-1.02, 1.24)]	0.887
Week 16	6	4.9 (2.63)		6	4.5 (2.25)			
Week 16 chg	6	-2.3 (1.83)	-1.79 (0.88)	6	-1.3 (1.76)	-1.67 (0.85)	0.12 (-2.90, 3.14) [0.07 (-1.06, 1.20)]	0.930
Week 17	6	4.7 (3.05)		6	4.7 (2.44)			
Week 17 chg	6	-2.5 (1.84)	-2.15 (0.88)	6	-1.1 (1.76)	-1.40 (0.85)	0.75 (-2.27, 3.77) [0.42 (-0.73, 1.56)]	0.588
Week 18	6	4.7 (2.79)		6	4.6 (2.45)			
Week 18 chg	6	-2.5 (1.89)	-2.01 (0.88)	6	-1.2 (2.03)	-1.60 (0.85)	0.41 (-2.61, 3.43) [0.21 (-0.93, 1.34)]	0.767
Week 19	6	4.4 (3.21)		6	4.3 (2.10)			
Week 19 chg	6	-2.8 (1.82)	-2.43 (0.88)	6	-1.5 (1.96)	-1.80 (0.85)	0.63 (-2.38, 3.65) [0.33 (-0.81, 1.47)]	0.648
Week 20	6	5.0 (2.79)		6	4.6 (2.21)			
Week 20 chg	6	-2.2 (1.25)	-1.85 (0.88)	6	-1.3 (1.50)	-1.54 (0.85)	0.31 (-2.71, 3.32) [0.22 (-0.91, 1.36)]	0.825
Week 21	5	3.8 (2.45)		6	4.8 (2.41)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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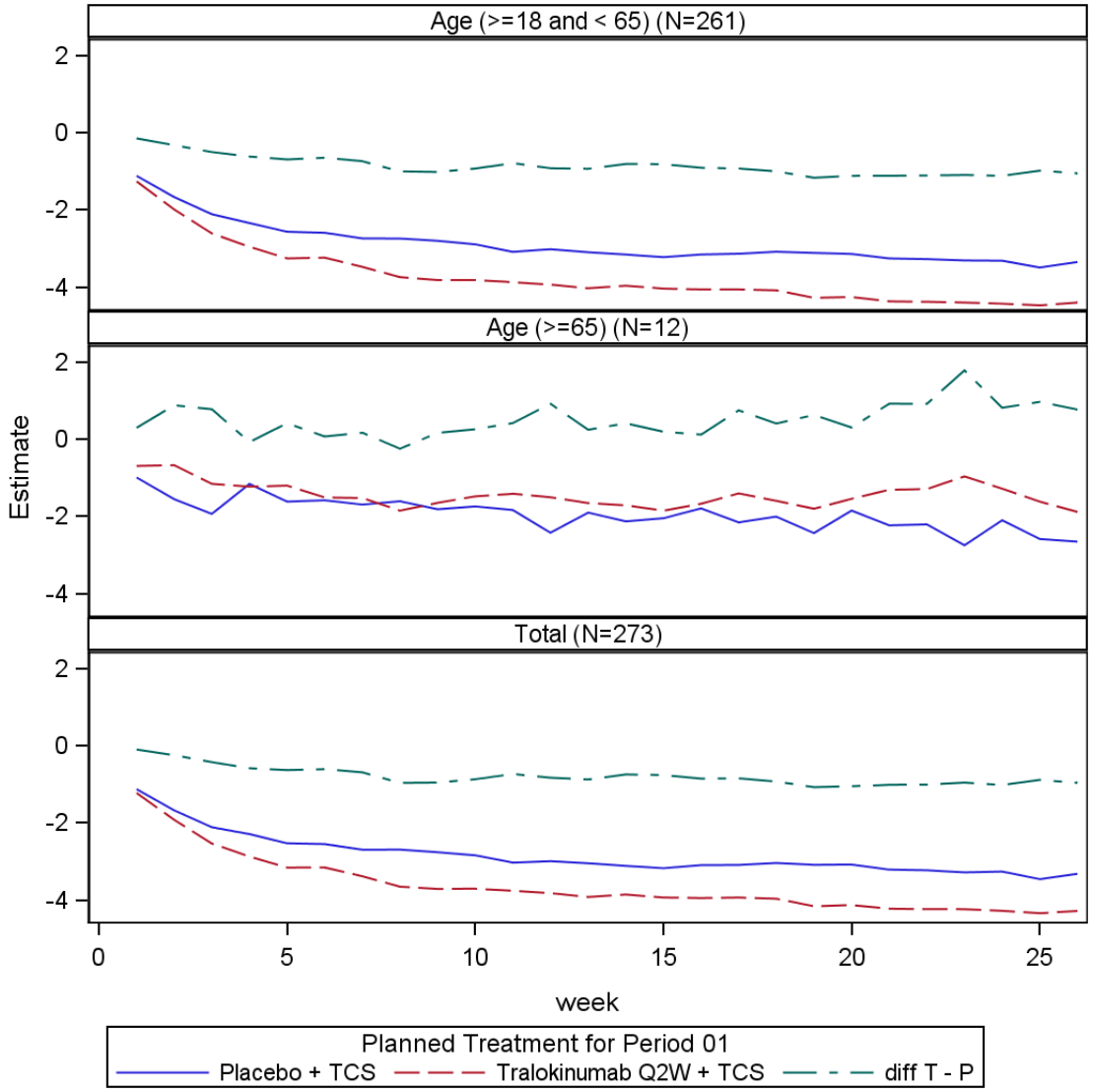
Table 1.3.416.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	5	-2.8 (1.58)	-2.23 (0.89)	6	-1.0 (1.96)	-1.31 (0.85)	0.92 (-2.10, 3.94) 0.509 [0.51 (-0.69, 1.72)]
Week 22	5	3.9 (2.96)		6	4.8 (2.33)		
Week 22 chg	5	-2.8 (2.23)	-2.21 (0.89)	6	-1.0 (1.82)	-1.29 (0.85)	0.92 (-2.10, 3.94) 0.511 [0.46 (-0.75, 1.66)]
Week 23	5	3.3 (2.90)		6	5.1 (2.54)		
Week 23 chg	5	-3.3 (1.80)	-2.75 (0.89)	6	-0.7 (2.24)	-0.96 (0.85)	1.79 (-1.23, 4.81) 0.215 [0.87 (-0.37, 2.11)]
Week 24	5	3.9 (3.28)		6	4.9 (2.61)		
Week 24 chg	5	-2.7 (2.64)	-2.10 (0.89)	6	-0.9 (2.39)	-1.28 (0.85)	0.82 (-2.20, 3.84) 0.557 [0.33 (-0.87, 1.52)]
Week 25	4	2.7 (2.17)		6	4.4 (2.81)		
Week 25 chg	4	-3.5 (2.07)	-2.59 (0.91)	6	-1.4 (1.69)	-1.62 (0.86)	0.97 (-2.06, 4.00) 0.490 [0.53 (-0.76, 1.81)]
Week 26	4	2.6 (2.16)		6	4.3 (2.45)		
Week 26 chg	4	-3.5 (2.30)	-2.65 (0.91)	6	-1.6 (1.67)	-1.88 (0.86)	0.77 (-2.26, 3.80) 0.582 [0.40 (-0.88, 1.68)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1693
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.416.4.2: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.3.418.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)			
Week 1		135 5.8 (2.01)			136 5.2 (2.21)			
Week 1 chg		135 -1.1 (1.50)	-1.05 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.10 (-0.61, 0.42) [-0.07 (-0.30, 0.17)]	0.715
Week 2		134 5.2 (2.29)			132 4.5 (2.45)			
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.19)	-0.18 (-0.70, 0.34) [-0.09 (-0.33, 0.15)]	0.502
Week 3		133 4.7 (2.36)			131 3.9 (2.35)			
Week 3 chg		133 -2.2 (2.17)	-2.12 (0.19)		131 -2.4 (2.01)	-2.49 (0.19)	-0.37 (-0.89, 0.15) [-0.18 (-0.42, 0.07)]	0.165
Week 4		130 4.5 (2.48)			133 3.6 (2.39)			
Week 4 chg		130 -2.4 (2.23)	-2.25 (0.19)		133 -2.7 (2.06)	-2.79 (0.19)	-0.54 (-1.06, -0.02) [-0.25 (-0.50, -0.01)]	0.041
Week 5		131 4.2 (2.55)			129 3.3 (2.42)			
Week 5 chg		131 -2.7 (2.37)	-2.54 (0.19)		129 -3.0 (2.16)	-3.13 (0.19)	-0.59 (-1.11, -0.07) [-0.26 (-0.50, -0.01)]	0.027
Week 6		130 4.2 (2.52)			129 3.3 (2.42)			
Week 6 chg		130 -2.7 (2.36)	-2.50 (0.19)		129 -3.1 (2.24)	-3.21 (0.19)	-0.71 (-1.23, -0.19) [-0.31 (-0.55, -0.06)]	0.008

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.418.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	3.9 (2.43)		128	3.1 (2.37)			
Week 7 chg	129	-3.0 (2.38)	-2.77 (0.19)	128	-3.3 (2.28)	-3.41 (0.19)	-0.64 (-1.16, -0.12) [-0.27 (-0.52, -0.03)]	0.016
Week 8	127	3.9 (2.46)		125	2.8 (2.29)			
Week 8 chg	127	-3.0 (2.32)	-2.75 (0.19)	125	-3.6 (2.26)	-3.65 (0.19)	-0.90 (-1.42, -0.38) [-0.39 (-0.64, -0.14)]	<.001
Week 9	127	3.8 (2.49)		127	2.6 (2.22)			
Week 9 chg	127	-3.1 (2.33)	-2.89 (0.19)	127	-3.7 (2.23)	-3.84 (0.19)	-0.95 (-1.47, -0.43) [-0.41 (-0.66, -0.17)]	<.001
Week 10	125	3.7 (2.54)		122	2.7 (2.29)			
Week 10 chg	125	-3.2 (2.40)	-3.00 (0.19)	122	-3.7 (2.29)	-3.82 (0.19)	-0.82 (-1.34, -0.30) [-0.35 (-0.60, -0.10)]	0.002
Week 11	128	3.6 (2.46)		126	2.6 (2.22)			
Week 11 chg	128	-3.3 (2.40)	-3.11 (0.19)	126	-3.8 (2.26)	-3.90 (0.19)	-0.78 (-1.31, -0.26) [-0.34 (-0.58, -0.09)]	0.003
Week 12	123	3.5 (2.44)		121	2.5 (2.21)			
Week 12 chg	123	-3.4 (2.45)	-3.14 (0.19)	121	-3.8 (2.38)	-4.00 (0.19)	-0.86 (-1.38, -0.33) [-0.36 (-0.61, -0.10)]	0.001
Week 13	116	3.4 (2.40)		120	2.3 (2.13)			
Week 13 chg	116	-3.6 (2.32)	-3.27 (0.19)	120	-3.9 (2.26)	-4.04 (0.19)	-0.77 (-1.30, -0.25) [-0.34 (-0.59, -0.08)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.418.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	123	3.3 (2.42)		123	2.4 (2.18)		
Week 14 chg	123	-3.5 (2.33)	-3.34 (0.19)	123	-3.9 (2.27)	-4.04 (0.19)	-0.70 (-1.22, -0.18) 0.009 [-0.30 (-0.56, -0.05)]
Week 15	123	3.3 (2.47)		123	2.4 (2.18)		
Week 15 chg	123	-3.7 (2.35)	-3.43 (0.19)	123	-3.9 (2.35)	-4.08 (0.19)	-0.65 (-1.17, -0.12) 0.015 [-0.28 (-0.53, -0.02)]
Week 16	121	3.2 (2.40)		122	2.5 (2.17)		
Week 16 chg	121	-3.7 (2.28)	-3.40 (0.19)	122	-3.9 (2.32)	-4.07 (0.19)	-0.67 (-1.20, -0.15) 0.012 [-0.29 (-0.55, -0.04)]
Week 17	121	3.4 (2.55)		121	2.4 (2.30)		
Week 17 chg	121	-3.6 (2.46)	-3.34 (0.19)	121	-4.0 (2.36)	-4.10 (0.19)	-0.76 (-1.28, -0.23) 0.005 [-0.31 (-0.57, -0.06)]
Week 18	120	3.4 (2.65)		123	2.3 (2.24)		
Week 18 chg	120	-3.6 (2.51)	-3.35 (0.19)	123	-4.0 (2.40)	-4.15 (0.19)	-0.79 (-1.31, -0.27) 0.003 [-0.32 (-0.58, -0.07)]
Week 19	119	3.3 (2.75)		117	2.2 (2.22)		
Week 19 chg	119	-3.7 (2.57)	-3.42 (0.19)	117	-4.1 (2.46)	-4.23 (0.19)	-0.81 (-1.33, -0.28) 0.003 [-0.32 (-0.58, -0.06)]
Week 20	120	3.4 (2.78)		118	2.2 (2.12)		
Week 20 chg	120	-3.6 (2.63)	-3.32 (0.19)	118	-4.1 (2.42)	-4.18 (0.19)	-0.87 (-1.39, -0.34) 0.001 [-0.34 (-0.60, -0.09)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.418.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21	118	3.2 (2.67)		115	2.1 (2.04)		
Week 21 chg	118	-3.8 (2.62)	-3.49 (0.19)	115	-4.2 (2.37)	-4.32 (0.19)	-0.83 (-1.36, -0.30) 0.002 [-0.33 (-0.59, -0.07)]
Week 22	120	3.3 (2.72)		116	2.0 (1.98)		
Week 22 chg	120	-3.7 (2.65)	-3.37 (0.19)	116	-4.3 (2.35)	-4.38 (0.19)	-1.00 (-1.53, -0.48) <.001 [-0.40 (-0.66, -0.14)]
Week 23	120	3.2 (2.64)		114	2.0 (2.02)		
Week 23 chg	120	-3.7 (2.56)	-3.45 (0.19)	114	-4.2 (2.44)	-4.35 (0.19)	-0.90 (-1.43, -0.37) <.001 [-0.36 (-0.62, -0.10)]
Week 24	120	3.2 (2.59)		112	2.0 (1.91)		
Week 24 chg	120	-3.8 (2.57)	-3.52 (0.19)	112	-4.2 (2.37)	-4.38 (0.19)	-0.86 (-1.39, -0.34) 0.001 [-0.35 (-0.61, -0.09)]
Week 25	114	2.8 (2.49)		115	2.0 (1.97)		
Week 25 chg	114	-4.1 (2.53)	-3.71 (0.19)	115	-4.3 (2.44)	-4.41 (0.19)	-0.70 (-1.23, -0.17) 0.010 [-0.28 (-0.54, -0.02)]
Week 26	112	2.9 (2.50)		118	2.1 (1.98)		
Week 26 chg	112	-4.0 (2.55)	-3.62 (0.19)	118	-4.2 (2.48)	-4.34 (0.19)	-0.72 (-1.25, -0.19) 0.008 [-0.29 (-0.55, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
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Table 1.3.418.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)										
Baseline	131	130	6.9 (1.62)		132	131	6.4 (2.09)			
Week 1		129	5.8 (2.02)			130	5.2 (2.20)			
Week 1 chg		129	-1.1 (1.52)	-1.04 (0.19)		130	-1.1 (1.44)	-1.17 (0.19)	-0.13 (-0.65, 0.39) [-0.09 (-0.33, 0.16)]	0.624
Week 2		128	5.2 (2.30)			126	4.5 (2.47)			
Week 2 chg		128	-1.7 (2.02)	-1.67 (0.19)		126	-1.8 (1.78)	-1.90 (0.19)	-0.24 (-0.76, 0.29) [-0.12 (-0.37, 0.12)]	0.376
Week 3		127	4.7 (2.37)			125	3.9 (2.37)			
Week 3 chg		127	-2.2 (2.19)	-2.12 (0.19)		125	-2.5 (1.98)	-2.55 (0.19)	-0.43 (-0.96, 0.09) [-0.21 (-0.45, 0.04)]	0.104
Week 4		124	4.5 (2.47)			127	3.6 (2.40)			
Week 4 chg		124	-2.4 (2.26)	-2.29 (0.19)		127	-2.8 (2.01)	-2.87 (0.19)	-0.59 (-1.11, -0.06) [-0.27 (-0.52, -0.03)]	0.028
Week 5		125	4.2 (2.56)			123	3.3 (2.42)			
Week 5 chg		125	-2.7 (2.41)	-2.56 (0.19)		123	-3.2 (2.08)	-3.23 (0.19)	-0.67 (-1.19, -0.15) [-0.30 (-0.55, -0.05)]	0.012
Week 6		124	4.2 (2.52)			123	3.2 (2.43)			
Week 6 chg		124	-2.7 (2.39)	-2.52 (0.19)		123	-3.2 (2.19)	-3.31 (0.19)	-0.79 (-1.31, -0.26) [-0.34 (-0.59, -0.09)]	0.003
Week 7		123	3.9 (2.44)			122	3.0 (2.36)			

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Table 1.3.418.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	123	-3.0 (2.41)	-2.79 (0.19)	122	-3.4 (2.20)	-3.51 (0.19)	-0.73 (-1.25, -0.20) [-0.31 (-0.57, -0.06)]	0.007
Week 8	121	3.9 (2.44)		119	2.7 (2.29)			
Week 8 chg	121	-3.0 (2.34)	-2.79 (0.19)	119	-3.7 (2.17)	-3.77 (0.19)	-0.97 (-1.50, -0.45) [-0.43 (-0.69, -0.17)]	<.001
Week 9	121	3.8 (2.48)		121	2.6 (2.20)			
Week 9 chg	121	-3.1 (2.36)	-2.93 (0.19)	121	-3.9 (2.14)	-3.96 (0.19)	-1.03 (-1.56, -0.51) [-0.46 (-0.71, -0.20)]	<.001
Week 10	119	3.7 (2.52)		116	2.6 (2.26)			
Week 10 chg	119	-3.2 (2.42)	-3.05 (0.19)	116	-3.9 (2.12)	-3.97 (0.19)	-0.92 (-1.44, -0.39) [-0.40 (-0.66, -0.14)]	<.001
Week 11	122	3.6 (2.43)		120	2.5 (2.20)			
Week 11 chg	122	-3.3 (2.42)	-3.16 (0.19)	120	-3.9 (2.15)	-4.03 (0.19)	-0.86 (-1.39, -0.34) [-0.38 (-0.63, -0.12)]	0.001
Week 12	118	3.5 (2.48)		115	2.4 (2.18)			
Week 12 chg	118	-3.4 (2.47)	-3.16 (0.19)	115	-4.0 (2.24)	-4.13 (0.19)	-0.97 (-1.50, -0.44) [-0.41 (-0.67, -0.15)]	<.001
Week 13	111	3.4 (2.43)		114	2.2 (2.11)			
Week 13 chg	111	-3.6 (2.35)	-3.31 (0.19)	114	-4.1 (2.16)	-4.17 (0.19)	-0.86 (-1.39, -0.33) [-0.38 (-0.64, -0.12)]	0.002
Week 14	118	3.4 (2.45)		118	2.3 (2.18)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
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Table 1.3.418.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	118	-3.5 (2.37)	-3.37 (0.19)	118	-4.0 (2.18)	-4.15 (0.19)	-0.79 (-1.31, -0.26) [-0.35 (-0.60, -0.09)]	0.004
Week 15	117	3.3 (2.47)		117	2.3 (2.17)			
Week 15 chg	117	-3.7 (2.38)	-3.47 (0.19)	117	-4.1 (2.18)	-4.20 (0.19)	-0.74 (-1.27, -0.21) [-0.32 (-0.58, -0.07)]	0.006
Week 16	115	3.2 (2.39)		116	2.4 (2.15)			
Week 16 chg	115	-3.7 (2.29)	-3.43 (0.19)	116	-4.1 (2.17)	-4.20 (0.19)	-0.76 (-1.29, -0.23) [-0.34 (-0.60, -0.08)]	0.005
Week 17	115	3.4 (2.55)		115	2.3 (2.26)			
Week 17 chg	115	-3.6 (2.50)	-3.38 (0.19)	115	-4.1 (2.16)	-4.25 (0.19)	-0.87 (-1.40, -0.34) [-0.37 (-0.63, -0.11)]	0.001
Week 18	114	3.4 (2.66)		117	2.2 (2.20)			
Week 18 chg	114	-3.6 (2.53)	-3.40 (0.19)	117	-4.2 (2.21)	-4.29 (0.19)	-0.89 (-1.42, -0.36) [-0.38 (-0.64, -0.11)]	0.001
Week 19	113	3.3 (2.75)		111	2.1 (2.20)			
Week 19 chg	113	-3.7 (2.62)	-3.45 (0.19)	111	-4.3 (2.29)	-4.35 (0.19)	-0.91 (-1.44, -0.37) [-0.37 (-0.63, -0.10)]	<.001
Week 20	114	3.4 (2.80)		112	2.1 (2.08)			
Week 20 chg	114	-3.6 (2.68)	-3.35 (0.19)	112	-4.3 (2.27)	-4.32 (0.19)	-0.97 (-1.50, -0.44) [-0.39 (-0.65, -0.13)]	<.001
Week 21	113	3.2 (2.71)		109	2.0 (1.97)			

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Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 21 chg	113	-3.8 (2.66)	-3.52 (0.19)	109	-4.4 (2.19)	-4.47 (0.19)	-0.95 (-1.49, -0.42) [-0.39 (-0.66, -0.12)]	<.001
Week 22	115	3.4 (2.76)		110	1.9 (1.93)			
Week 22 chg	115	-3.6 (2.70)	-3.39 (0.19)	110	-4.5 (2.21)	-4.51 (0.19)	-1.12 (-1.65, -0.59) [-0.45 (-0.72, -0.19)]	<.001
Week 23	115	3.3 (2.67)		108	1.9 (1.93)			
Week 23 chg	115	-3.7 (2.61)	-3.45 (0.19)	108	-4.4 (2.27)	-4.50 (0.19)	-1.05 (-1.58, -0.52) [-0.43 (-0.69, -0.16)]	<.001
Week 24	115	3.2 (2.61)		106	1.9 (1.81)			
Week 24 chg	115	-3.8 (2.61)	-3.55 (0.19)	106	-4.4 (2.17)	-4.53 (0.19)	-0.98 (-1.51, -0.45) [-0.41 (-0.67, -0.14)]	<.001
Week 25	110	2.9 (2.52)		109	1.9 (1.90)			
Week 25 chg	110	-4.1 (2.56)	-3.73 (0.19)	109	-4.4 (2.28)	-4.54 (0.19)	-0.81 (-1.34, -0.27) [-0.33 (-0.60, -0.07)]	0.003
Week 26	108	3.0 (2.52)		112	2.0 (1.95)			
Week 26 chg	108	-4.0 (2.58)	-3.64 (0.19)	112	-4.3 (2.36)	-4.45 (0.19)	-0.81 (-1.34, -0.28) [-0.33 (-0.59, -0.06)]	0.003

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Age (>=65)								
Baseline	6	6 7.0 (2.34)		6	6 5.0 (2.30)			
Week 1		6 5.5 (1.90)			6 4.6 (2.56)			
Week 1 chg		6 -1.4 (0.85)	-0.98 (0.90)		6 -0.4 (1.61)	-0.82 (0.87)	0.16 (-2.88, 3.19) [0.12 (-1.01, 1.26)]	0.911
Week 2		6 5.0 (2.31)			6 4.7 (2.19)			
Week 2 chg		6 -1.9 (1.14)	-1.45 (0.90)		6 -0.4 (1.68)	-0.79 (0.87)	0.66 (-2.38, 3.70) [0.46 (-0.69, 1.60)]	0.642
Week 3		6 4.3 (2.30)			6 4.3 (2.05)			
Week 3 chg		6 -2.6 (1.71)	-1.93 (0.90)		6 -0.8 (2.11)	-1.34 (0.87)	0.59 (-2.45, 3.62) [0.31 (-0.83, 1.44)]	0.679
Week 4		6 5.0 (2.84)			6 4.2 (2.12)			
Week 4 chg		6 -1.9 (1.34)	-1.40 (0.90)		6 -0.8 (2.35)	-1.24 (0.87)	0.16 (-2.88, 3.19) [0.08 (-1.05, 1.21)]	0.912
Week 5		6 4.3 (2.46)			6 4.5 (2.29)			
Week 5 chg		6 -2.6 (1.47)	-1.96 (0.90)		6 -0.6 (2.55)	-1.12 (0.87)	0.83 (-2.20, 3.87) [0.40 (-0.74, 1.54)]	0.558
Week 6		6 4.5 (2.76)			6 4.3 (2.21)			
Week 6 chg		6 -2.5 (1.47)	-1.96 (0.90)		6 -0.7 (2.18)	-1.13 (0.87)	0.83 (-2.20, 3.87) [0.45 (-0.70, 1.59)]	0.558
Week 7		6 4.0 (2.37)			6 4.3 (2.26)			

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Week 7 chg	6	-3.0 (1.91)	-2.24 (0.90)	6	-0.7 (2.39)	-1.31 (0.87)	0.93 (-2.11, 3.97) 0.514 [0.43 (-0.72, 1.57)]
Week 8	6	4.5 (2.98)		6	4.2 (1.97)		
Week 8 chg	6	-2.4 (1.91)	-1.76 (0.90)	6	-0.8 (2.45)	-1.33 (0.87)	0.43 (-2.60, 3.47) 0.759 [0.20 (-0.94, 1.33)]
Week 9	6	4.3 (2.82)		6	4.2 (1.98)		
Week 9 chg	6	-2.7 (1.88)	-2.05 (0.90)	6	-0.8 (2.25)	-1.32 (0.87)	0.73 (-2.31, 3.77) 0.607 [0.35 (-0.79, 1.49)]
Week 10	6	4.5 (3.16)		6	4.8 (2.20)		
Week 10 chg	6	-2.5 (1.92)	-1.81 (0.90)	6	-0.2 (3.01)	-0.80 (0.87)	1.01 (-2.03, 4.04) 0.481 [0.40 (-0.74, 1.54)]
Week 11	6	4.3 (3.18)		6	4.3 (2.08)		
Week 11 chg	6	-2.6 (1.84)	-2.07 (0.90)	6	-0.7 (2.43)	-1.21 (0.87)	0.86 (-2.18, 3.89) 0.548 [0.40 (-0.75, 1.54)]
Week 12	5	2.7 (1.27)		6	4.4 (2.15)		
Week 12 chg	5	-3.7 (2.12)	-2.54 (0.91)	6	-0.6 (2.90)	-1.43 (0.87)	1.10 (-1.94, 4.14) 0.442 [0.43 (-0.77, 1.63)]
Week 13	5	3.1 (1.63)		6	4.1 (1.75)		
Week 13 chg	5	-3.4 (1.79)	-2.32 (0.91)	6	-1.0 (2.36)	-1.60 (0.87)	0.72 (-2.32, 3.76) 0.613 [0.34 (-0.86, 1.53)]
Week 14	5	2.8 (1.62)		5	3.9 (1.81)		

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Test for treatment and subgroup interaction: 0.0107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.418.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	5	-3.7 (1.48)	-2.59 (0.91)	5	-1.2 (2.85)	-1.79 (0.89)	0.79 (-2.26, 3.85) 0.581 [0.35 (-0.90, 1.60)]
Week 15	6	3.5 (2.76)		6	4.1 (1.86)		
Week 15 chg	6	-3.5 (1.96)	-2.44 (0.90)	6	-0.9 (3.51)	-1.76 (0.87)	0.69 (-2.35, 3.72) 0.629 [0.24 (-0.89, 1.38)]
Week 16	6	3.6 (2.67)		6	4.2 (1.82)		
Week 16 chg	6	-3.3 (2.07)	-2.32 (0.90)	6	-0.8 (3.24)	-1.62 (0.87)	0.69 (-2.34, 3.73) 0.626 [0.25 (-0.88, 1.39)]
Week 17	6	3.5 (2.69)		6	4.5 (2.20)		
Week 17 chg	6	-3.4 (1.59)	-2.47 (0.90)	6	-0.5 (3.50)	-1.28 (0.87)	1.19 (-1.85, 4.22) 0.408 [0.44 (-0.71, 1.58)]
Week 18	6	3.6 (2.71)		6	4.4 (2.17)		
Week 18 chg	6	-3.3 (2.08)	-2.27 (0.90)	6	-0.6 (3.51)	-1.43 (0.87)	0.84 (-2.20, 3.88) 0.555 [0.29 (-0.85, 1.43)]
Week 19	6	3.4 (2.85)		6	4.0 (1.98)		
Week 19 chg	6	-3.6 (1.69)	-2.60 (0.90)	6	-1.0 (3.55)	-1.78 (0.87)	0.83 (-2.21, 3.86) 0.562 [0.30 (-0.84, 1.43)]
Week 20	6	3.7 (2.59)		6	4.3 (1.95)		
Week 20 chg	6	-3.2 (1.60)	-2.40 (0.90)	6	-0.8 (2.94)	-1.45 (0.87)	0.96 (-2.08, 3.99) 0.502 [0.40 (-0.74, 1.55)]
Week 21	5	2.5 (1.51)		6	4.3 (2.14)		

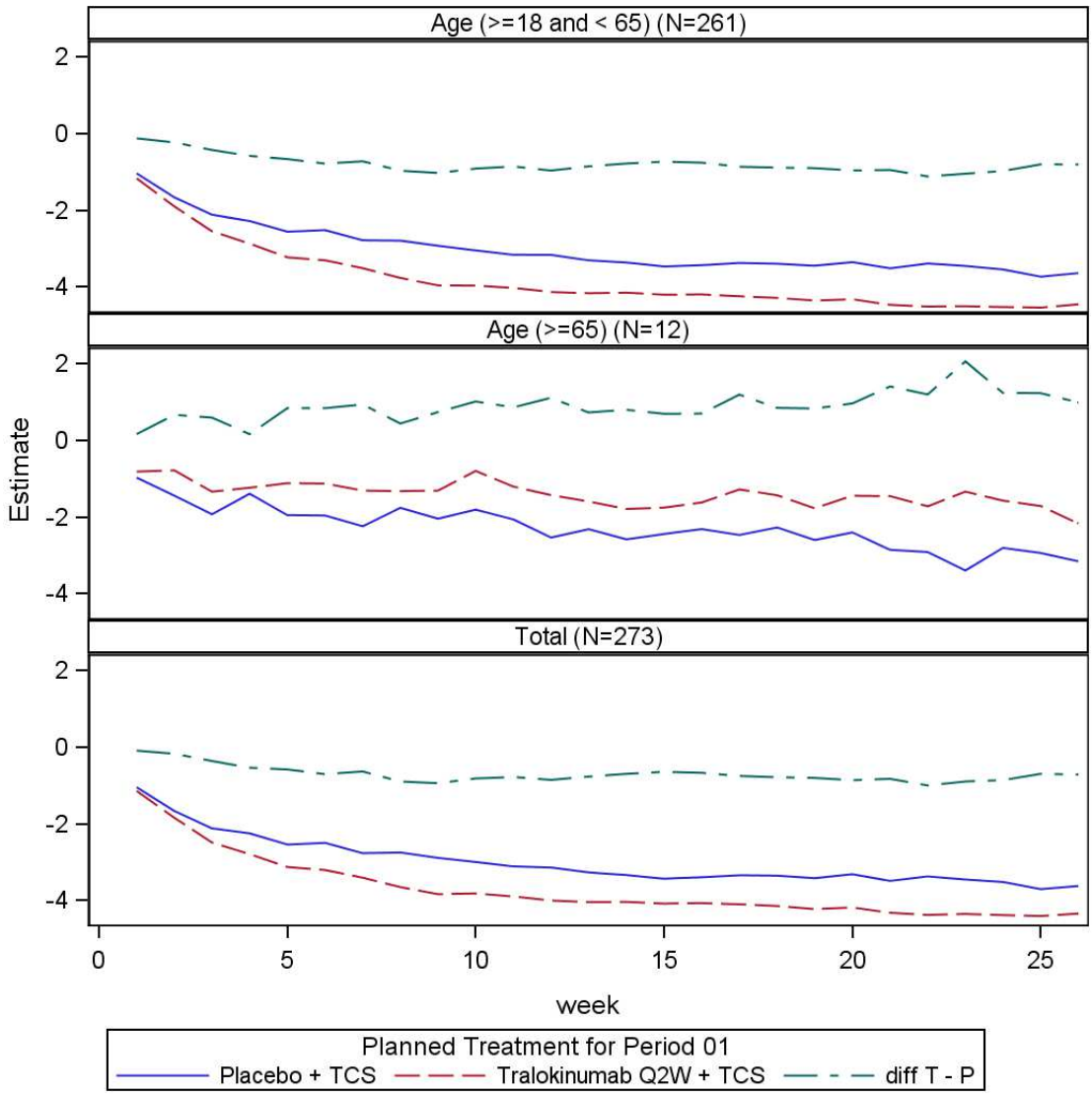
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.418.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	5	-4.0 (1.64)	-2.86 (0.91)	6	-0.7 (3.04)	-1.46 (0.87)	1.40 (-1.64, 4.44) 0.333 [0.56 (-0.65, 1.77)]
Week 22	5	2.5 (1.72)		6	4.0 (1.97)		
Week 22 chg	5	-4.0 (1.55)	-2.92 (0.91)	6	-1.1 (2.72)	-1.72 (0.87)	1.19 (-1.85, 4.23) 0.407 [0.52 (-0.68, 1.73)]
Week 23	5	2.0 (1.79)		6	4.3 (2.36)		
Week 23 chg	5	-4.4 (0.92)	-3.40 (0.91)	6	-0.7 (3.13)	-1.34 (0.87)	2.06 (-0.99, 5.10) 0.165 [0.85 (-0.39, 2.09)]
Week 24	5	2.5 (1.94)		6	4.2 (2.39)		
Week 24 chg	5	-3.9 (1.59)	-2.81 (0.91)	6	-0.8 (3.45)	-1.58 (0.87)	1.23 (-1.81, 4.27) 0.393 [0.44 (-0.76, 1.64)]
Week 25	4	1.9 (1.34)		6	4.0 (2.37)		
Week 25 chg	4	-3.9 (1.76)	-2.94 (0.94)	6	-1.0 (3.13)	-1.72 (0.88)	1.23 (-1.83, 4.28) 0.397 [0.45 (-0.83, 1.73)]
Week 26	4	1.7 (1.30)		6	3.7 (1.97)		
Week 26 chg	4	-4.1 (1.76)	-3.16 (0.94)	6	-1.4 (3.17)	-2.17 (0.88)	0.98 (-2.07, 4.03) 0.494 [0.36 (-0.91, 1.64)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0107
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.418.4.2: Total, Age group, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.3.420.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.24 (1.50)		138 -20.9 (16.72)	-21.09 (1.49)	-3.85 (-8.01, 0.31) 0.070 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.30 (1.51)		137 -30.8 (17.25)	-31.04 (1.50)	-4.74 (-8.92, -0.57) 0.026 [-0.27 (-0.50, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.83 (1.51)		134 -34.3 (17.49)	-34.46 (1.50)	-7.63 (-11.8, -3.43) <.001 [-0.42 (-0.66, -0.17)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.66 (1.51)		130 -36.6 (18.48)	-36.77 (1.51)	-8.11 (-12.3, -3.91) <.001 [-0.42 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.81 (1.51)		130 -38.5 (19.49)	-38.57 (1.51)	-7.76 (-12.0, -3.55) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.59 (1.52)		128 -39.5 (18.74)	-39.57 (1.52)	-7.98 (-12.2, -3.76) <.001 [-0.42 (-0.66, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4144
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.420.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 36.0 (19.61)			127 28.3 (17.87)		
Week 14 chg		126 -34.8 (20.31)	-34.25 (1.53)		127 -41.8 (20.11)	-41.39 (1.52)	-7.14 (-11.4, -2.91) <.001 [-0.35 (-0.60, -0.11)]
Week 16		124 36.3 (18.78)			123 27.0 (16.90)		
Week 16 chg		124 -34.7 (19.94)	-33.90 (1.53)		123 -43.3 (19.46)	-42.70 (1.53)	-8.80 (-13.0, -4.55) <.001 [-0.45 (-0.70, -0.19)]
Week 18		116 36.8 (19.98)			115 25.1 (15.97)		
Week 18 chg		116 -34.1 (20.70)	-33.27 (1.55)		115 -44.8 (19.27)	-43.62 (1.55)	-10.36 (-14.7, -6.05) <.001 [-0.52 (-0.78, -0.26)]
Week 20		107 35.7 (19.63)			117 25.6 (16.83)		
Week 20 chg		107 -35.6 (20.01)	-34.07 (1.57)		117 -44.9 (18.80)	-43.48 (1.54)	-9.41 (-13.7, -5.08) <.001 [-0.49 (-0.75, -0.22)]
Week 22		112 35.6 (20.27)			114 23.3 (14.77)		
Week 22 chg		112 -35.5 (20.64)	-34.08 (1.56)		114 -46.8 (19.03)	-45.23 (1.55)	-11.15 (-15.5, -6.83) <.001 [-0.56 (-0.83, -0.30)]
Week 24		112 34.6 (19.86)			117 23.3 (15.61)		
Week 24 chg		112 -36.5 (20.30)	-34.56 (1.56)		117 -46.9 (18.55)	-45.65 (1.54)	-11.09 (-15.4, -6.78) <.001 [-0.57 (-0.84, -0.31)]
Week 26		118 33.1 (18.32)			125 23.8 (16.51)		
Week 26 chg		118 -38.1 (19.21)	-36.22 (1.54)		125 -46.3 (19.60)	-45.94 (1.52)	-9.72 (-14.0, -5.46) <.001 [-0.50 (-0.76, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4144
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.3.420.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	131 70.8 (12.81)		132	132 70.3 (12.06)		
Week 2		131 53.3 (17.53)			132 48.9 (18.16)		
Week 2 chg		131 -17.5 (16.18)	-17.35 (1.49)		132 -21.4 (16.67)	-21.54 (1.49)	-4.19 (-8.33, -0.04) 0.048 [-0.25 (-0.50, -0.01)]
Week 4		128 43.7 (18.12)			131 38.6 (17.59)		
Week 4 chg		128 -26.9 (18.26)	-26.40 (1.50)		131 -31.5 (17.06)	-31.61 (1.49)	-5.21 (-9.37, -1.05) 0.014 [-0.30 (-0.54, -0.05)]
Week 6		126 43.3 (18.43)			128 35.6 (16.65)		
Week 6 chg		126 -27.5 (19.01)	-26.96 (1.51)		128 -34.5 (17.44)	-34.63 (1.50)	-7.66 (-11.8, -3.49) <.001 [-0.42 (-0.67, -0.17)]
Week 8		127 41.3 (19.30)			124 32.7 (16.64)		
Week 8 chg		127 -29.3 (19.46)	-28.97 (1.50)		124 -37.4 (17.96)	-37.44 (1.51)	-8.47 (-12.7, -4.29) <.001 [-0.45 (-0.70, -0.20)]
Week 10		125 39.0 (19.39)			124 30.4 (17.54)		
Week 10 chg		125 -31.7 (20.95)	-31.05 (1.51)		124 -39.5 (18.63)	-39.50 (1.51)	-8.45 (-12.6, -4.25) <.001 [-0.43 (-0.68, -0.17)]
Week 12		123 38.4 (17.44)			122 30.0 (17.26)		
Week 12 chg		123 -32.6 (19.41)	-31.96 (1.51)		122 -40.1 (18.26)	-40.07 (1.51)	-8.11 (-12.3, -3.90) <.001 [-0.43 (-0.68, -0.18)]
Week 14		120 35.6 (18.61)			121 27.6 (17.26)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4144
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.3.420.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	120	120 -35.1 (19.93)	-34.69 (1.52)	121	121 -42.6 (19.45)	-42.07 (1.52)	-7.38 (-11.6, -3.16) <.001 [-0.37 (-0.63, -0.12)]
Week 16	118	118 36.0 (17.61)		117	117 26.5 (16.64)		
Week 16 chg	118	118 -35.0 (19.51)	-34.20 (1.53)	117	117 -43.9 (19.01)	-43.13 (1.53)	-8.93 (-13.2, -4.69) <.001 [-0.46 (-0.72, -0.20)]
Week 18	110	110 36.4 (18.89)		110	110 24.8 (15.98)		
Week 18 chg	110	110 -34.4 (20.32)	-33.62 (1.55)	110	110 -45.2 (18.86)	-44.13 (1.54)	-10.51 (-14.8, -6.21) <.001 [-0.54 (-0.80, -0.27)]
Week 20	102	102 35.3 (18.27)		112	112 25.6 (16.89)		
Week 20 chg	102	102 -35.9 (19.48)	-34.58 (1.57)	112	112 -45.1 (18.49)	-43.71 (1.54)	-9.14 (-13.5, -4.82) <.001 [-0.48 (-0.75, -0.21)]
Week 22	108	108 36.0 (19.99)		109	109 23.1 (14.87)		
Week 22 chg	108	108 -35.2 (20.59)	-34.26 (1.55)	109	109 -47.1 (18.85)	-45.63 (1.55)	-11.37 (-15.7, -7.06) <.001 [-0.58 (-0.85, -0.30)]
Week 24	108	108 35.1 (19.78)		112	112 23.2 (15.70)		
Week 24 chg	108	108 -36.1 (20.43)	-34.61 (1.55)	112	112 -47.2 (18.24)	-46.02 (1.54)	-11.40 (-15.7, -7.11) <.001 [-0.59 (-0.86, -0.32)]
Week 26	114	114 33.6 (18.05)		119	119 23.2 (15.82)		
Week 26 chg	114	114 -37.7 (19.18)	-36.27 (1.54)	119	119 -47.0 (18.77)	-46.46 (1.52)	-10.20 (-14.4, -5.95) <.001 [-0.54 (-0.80, -0.28)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4144
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.420.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 72.3 (14.77)		6	6 68.4 (12.78)		
Week 2		6 55.9 (21.25)			6 58.2 (18.23)		
Week 2 chg		6 -16.5 (14.63)	-10.26 (9.34)		6 -10.2 (15.55)	-16.09 (9.26)	-5.83 (-36.0, 24.33) 0.678 [-0.39 (-1.53, 0.76)]
Week 4		6 46.4 (24.47)			6 51.4 (15.24)		
Week 4 chg		6 -26.0 (24.11)	-18.61 (9.34)		6 -17.0 (16.91)	-23.61 (9.26)	-5.00 (-35.2, 25.16) 0.722 [-0.24 (-1.38, 0.90)]
Week 6		6 46.3 (29.64)			6 39.1 (17.55)		
Week 6 chg		6 -26.0 (23.86)	-19.53 (9.34)		6 -29.3 (19.46)	-35.37 (9.26)	-15.84 (-46.0, 14.32) 0.272 [-0.73 (-1.90, 0.44)]
Week 8		6 48.4 (34.74)			6 47.6 (19.36)		
Week 8 chg		6 -23.9 (29.39)	-17.18 (9.34)		6 -20.8 (23.74)	-27.02 (9.26)	-9.84 (-40.0, 20.32) 0.488 [-0.37 (-1.51, 0.77)]
Week 10		6 44.4 (31.54)			6 51.2 (21.84)		
Week 10 chg		6 -27.9 (26.21)	-20.96 (9.34)		6 -17.2 (26.15)	-23.54 (9.26)	-2.58 (-32.7, 27.58) 0.854 [-0.10 (-1.23, 1.03)]
Week 12		5 44.1 (35.13)			6 41.2 (23.80)		
Week 12 chg		5 -29.7 (27.31)	-18.81 (9.64)		6 -27.2 (25.77)	-33.29 (9.26)	-14.48 (-44.9, 15.97) 0.320 [-0.55 (-1.76, 0.66)]
Week 14		6 45.0 (35.62)			6 42.9 (25.09)		

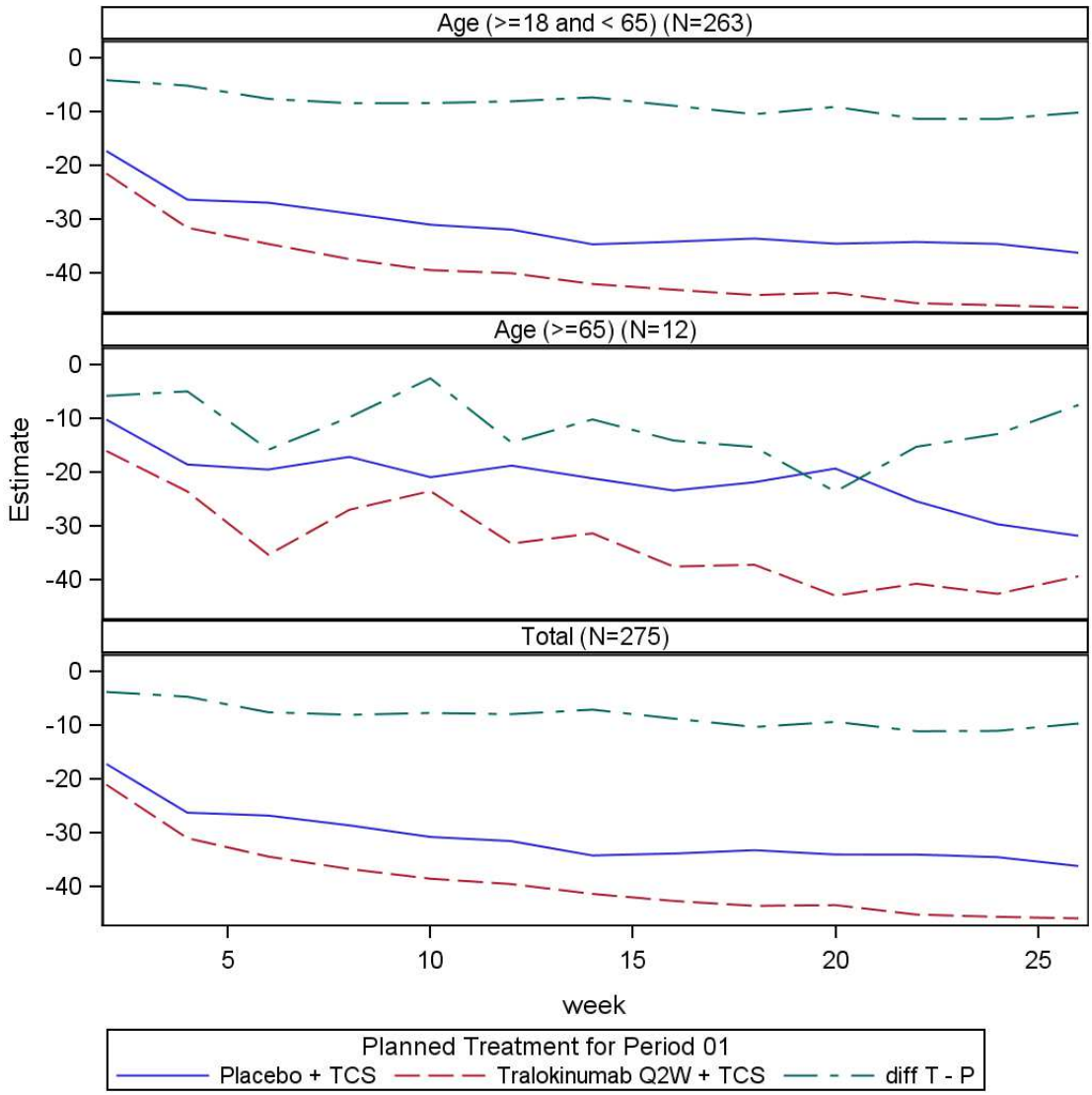
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4144
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.420.4.1: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	6	-27.4 (28.07)	-21.18 (9.34)	6	-25.5 (27.96)	-31.39 (9.26)	-10.21 (-40.4, 19.95) 0.472 [-0.36 (-1.51, 0.78)]
Week 16	6	42.5 (36.99)		6	36.8 (20.60)		
Week 16 chg	6	-29.8 (28.96)	-23.43 (9.34)	6	-31.6 (26.11)	-37.57 (9.26)	-14.13 (-44.3, 16.03) 0.324 [-0.51 (-1.66, 0.64)]
Week 18	6	43.8 (36.62)		5	30.9 (16.40)		
Week 18 chg	6	-28.5 (28.62)	-21.90 (9.34)	5	-36.2 (28.02)	-37.24 (9.52)	-15.34 (-45.7, 15.05) 0.292 [-0.54 (-1.75, 0.67)]
Week 20	5	43.6 (41.22)		5	25.0 (17.51)		
Week 20 chg	5	-30.2 (31.43)	-19.34 (9.65)	5	-42.1 (27.41)	-42.99 (9.52)	-23.65 (-54.3, 7.05) 0.119 [-0.80 (-2.09, 0.49)]
Week 22	4	25.5 (28.61)		5	27.2 (13.13)		
Week 22 chg	4	-43.1 (23.62)	-25.45 (9.95)	5	-39.9 (23.96)	-40.76 (9.53)	-15.31 (-46.2, 15.56) 0.303 [-0.64 (-1.99, 0.71)]
Week 24	4	21.6 (20.16)		5	25.9 (14.75)		
Week 24 chg	4	-47.0 (14.21)	-29.70 (9.95)	5	-41.2 (26.54)	-42.64 (9.53)	-12.94 (-43.8, 17.93) 0.381 [-0.58 (-1.93, 0.76)]
Week 26	4	19.4 (23.62)		6	35.4 (26.18)		
Week 26 chg	4	-49.2 (19.22)	-31.85 (9.95)	6	-33.1 (31.43)	-39.39 (9.26)	-7.54 (-38.2, 23.12) 0.603 [-0.27 (-1.54, 1.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4144
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.420.4.2: Total, Age group, change in SCORAD, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.3.422.4.1: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score									
Total									
Baseline	137	134	16.4 (6.33)		138	137	15.9 (6.53)		
Week 2		131	9.2 (6.47)			132	8.5 (6.17)		
Week 2 chg		131	-7.2 (5.73)	-7.13 (0.44)		132	-7.5 (5.92)	-7.54 (0.44)	-0.41 (-1.63, 0.81) 0.508 [-0.07 (-0.31, 0.17)]
Week 4		130	7.8 (6.27)			135	6.7 (5.98)		
Week 4 chg		130	-8.6 (6.67)	-8.30 (0.44)		135	-9.0 (6.32)	-9.13 (0.44)	-0.82 (-2.04, 0.40) 0.185 [-0.13 (-0.37, 0.11)]
Week 6		123	7.3 (6.07)			126	6.0 (5.79)		
Week 6 chg		123	-8.9 (7.23)	-8.60 (0.45)		126	-10.0 (6.75)	-9.85 (0.44)	-1.25 (-2.48, -0.01) 0.048 [-0.18 (-0.43, 0.07)]
Week 8		127	6.9 (5.70)			128	5.4 (5.11)		
Week 8 chg		127	-9.4 (6.84)	-8.94 (0.44)		128	-10.6 (6.29)	-10.36 (0.44)	-1.41 (-2.64, -0.19) 0.024 [-0.22 (-0.46, 0.03)]
Week 12		123	6.8 (5.89)			124	5.0 (3.92)		
Week 12 chg		123	-9.8 (7.26)	-9.29 (0.45)		124	-10.6 (5.77)	-10.55 (0.44)	-1.26 (-2.50, -0.02) 0.046 [-0.19 (-0.44, 0.06)]
Week 16		120	6.5 (5.63)			118	4.5 (3.88)		
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.45)		118	-11.0 (5.99)	-11.14 (0.45)	-1.46 (-2.71, -0.22) 0.022 [-0.23 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5490
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.422.4.1: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 20	102	6.2 (5.67)		111	4.1 (3.92)		
Week 20 chg	102	-9.9 (7.06)	-9.64 (0.46)	111	-11.4 (5.58)	-11.49 (0.45)	-1.85 (-3.13, -0.57) 0.005 [-0.29 (-0.56, -0.02)]
Week 26	110	6.3 (5.26)		116	4.3 (4.31)		
Week 26 chg	110	-10.4 (6.56)	-9.61 (0.46)	116	-11.1 (6.17)	-11.28 (0.45)	-1.67 (-2.93, -0.41) 0.010 [-0.26 (-0.52, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5490
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.422.4.1: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)											
Baseline	131	128	16.5 (6.34)			132	131	16.0 (6.43)			
Week 2		125	9.4 (6.53)				126	8.4 (6.28)			
Week 2 chg		125	-7.2 (5.75)	-7.08 (0.45)			126	-7.8 (5.74)	-7.78 (0.45)		-0.69 (-1.95, 0.56) 0.278 [-0.12 (-0.37, 0.13)]
Week 4		124	7.8 (6.36)				129	6.8 (6.07)			
Week 4 chg		124	-8.7 (6.74)	-8.44 (0.46)			129	-9.2 (6.20)	-9.25 (0.45)		-0.81 (-2.07, 0.45) 0.206 [-0.13 (-0.37, 0.12)]
Week 6		117	7.4 (6.04)				121	6.0 (5.90)			
Week 6 chg		117	-9.0 (7.38)	-8.66 (0.46)			121	-10.0 (6.77)	-9.97 (0.45)		-1.31 (-2.58, -0.04) 0.044 [-0.18 (-0.44, 0.07)]
Week 8		121	7.0 (5.77)				122	5.4 (5.21)			
Week 8 chg		121	-9.4 (6.94)	-8.98 (0.46)			122	-10.8 (6.11)	-10.55 (0.45)		-1.57 (-2.84, -0.31) 0.015 [-0.24 (-0.49, 0.01)]
Week 12		118	6.9 (5.95)				118	4.9 (3.96)			
Week 12 chg		118	-9.8 (7.38)	-9.34 (0.46)			118	-10.9 (5.51)	-10.79 (0.46)		-1.45 (-2.72, -0.17) 0.026 [-0.22 (-0.48, 0.03)]
Week 16		114	6.5 (5.59)				112	4.3 (3.81)			
Week 16 chg		114	-10.1 (6.64)	-9.78 (0.46)			112	-11.3 (5.68)	-11.41 (0.46)		-1.63 (-2.92, -0.35) 0.013 [-0.26 (-0.53, -0.00)]
Week 20		98	6.3 (5.75)				106	4.0 (3.89)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5490
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.422.4.1: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	98	-10.0 (7.15)	-9.73 (0.48)	106	-11.7 (5.39)	-11.71 (0.47)	-1.98 (-3.29, -0.67) [-0.31 (-0.59, -0.04)]	0.003
Week 26	106	6.4 (5.30)		110	4.2 (4.29)			
Week 26 chg	106	-10.4 (6.64)	-9.66 (0.47)	110	-11.4 (6.10)	-11.50 (0.46)	-1.84 (-3.14, -0.54) [-0.29 (-0.56, -0.02)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5490
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.422.4.1: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 13.7 (6.09)		6	6 12.3 (8.38)		
Week 2		6 5.0 (3.16)			6 10.0 (2.97)		
Week 2 chg		6 -8.7 (5.47)	-7.74 (1.33)		6 -2.3 (7.76)	-3.09 (1.33)	4.64 (0.55, 8.74) 0.028 [0.69 (-0.47, 1.86)]
Week 4		6 7.7 (4.37)			6 6.2 (4.07)		
Week 4 chg		6 -6.0 (4.90)	-5.09 (1.33)		6 -6.2 (8.75)	-6.91 (1.33)	-1.82 (-5.91, 2.28) 0.363 [-0.26 (-1.39, 0.88)]
Week 6		6 5.8 (7.08)			5 5.4 (1.95)		
Week 6 chg		6 -7.8 (3.25)	-7.15 (1.34)		5 -9.2 (6.76)	-8.29 (1.41)	-1.14 (-5.30, 3.02) 0.573 [-0.22 (-1.41, 0.97)]
Week 8		6 5.0 (4.10)			6 6.5 (2.26)		
Week 8 chg		6 -8.7 (4.72)	-7.72 (1.33)		6 -5.8 (8.70)	-6.60 (1.33)	1.11 (-2.98, 5.21) 0.573 [0.16 (-0.97, 1.29)]
Week 12		5 4.6 (4.39)			6 7.2 (2.32)		
Week 12 chg		5 -9.6 (3.51)	-8.02 (1.42)		6 -5.2 (8.42)	-5.90 (1.33)	2.12 (-2.09, 6.32) 0.306 [0.32 (-0.88, 1.51)]
Week 16		6 5.7 (6.86)			6 7.2 (4.45)		
Week 16 chg		6 -8.0 (4.05)	-7.22 (1.33)		6 -5.2 (9.02)	-5.82 (1.33)	1.40 (-2.70, 5.49) 0.482 [0.20 (-0.93, 1.33)]
Week 20		4 3.3 (1.50)			5 5.8 (4.55)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5490
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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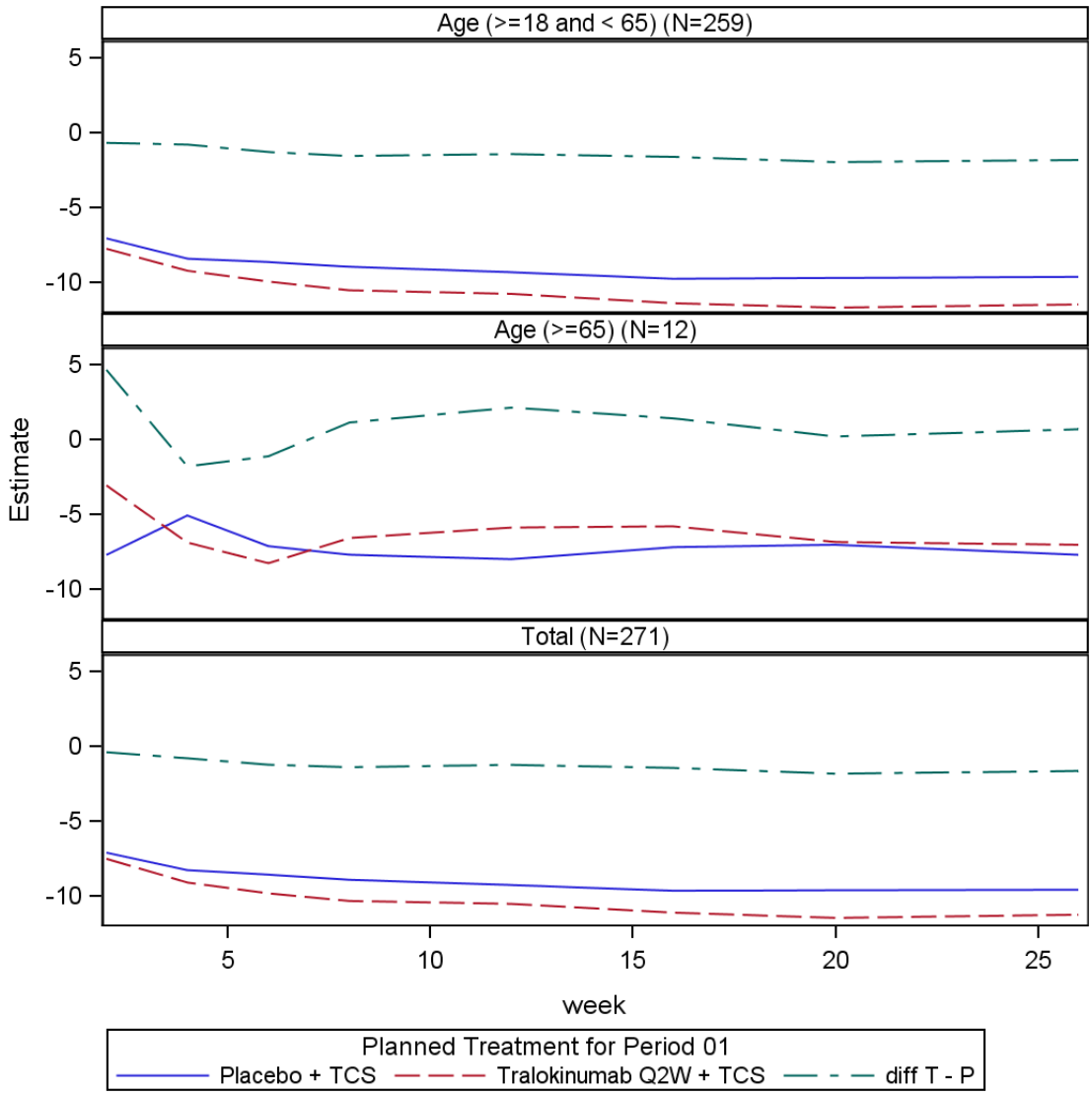
Table 1.3.422.4.1: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	4	-8.5 (4.43)	-7.06 (1.52)	5	-5.2 (6.57)	-6.87 (1.42)	0.18 (-4.20, 4.57) [0.03 (-1.28, 1.35)]	0.932
Week 26	4	2.5 (2.08)		6	5.8 (4.96)			
Week 26 chg	4	-9.3 (4.65)	-7.72 (1.52)	6	-6.5 (6.12)	-7.06 (1.33)	0.67 (-3.64, 4.97) [0.12 (-1.15, 1.38)]	0.751

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5490
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.422.4.2: Total, Age group, change in DLQI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.3.423.4.1: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total									
Total									
Baseline	137	134	20.9 (5.72)		138	135	21.3 (5.12)		
Week 2		130	15.1 (6.91)			130	13.5 (6.31)		
Week 2 chg		130	-5.9 (6.29)	-5.97 (0.55)		130	-7.7 (5.43)	-7.67 (0.55)	-1.71 (-3.23, -0.18) 0.029 [-0.29 (-0.53, -0.05)]
Week 4		130	13.8 (7.45)			133	11.6 (6.30)		
Week 4 chg		130	-7.1 (7.56)	-7.11 (0.55)		133	-9.7 (6.02)	-9.53 (0.55)	-2.42 (-3.94, -0.89) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123	13.5 (7.81)			124	10.9 (5.95)		
Week 6 chg		123	-7.2 (8.29)	-7.29 (0.56)		124	-10.6 (6.27)	-10.35 (0.56)	-3.07 (-4.61, -1.52) <.001 [-0.42 (-0.67, -0.17)]
Week 8		127	13.1 (7.02)			126	9.9 (5.79)		
Week 8 chg		127	-7.6 (7.95)	-7.70 (0.55)		126	-11.5 (6.10)	-11.16 (0.55)	-3.46 (-5.00, -1.92) <.001 [-0.49 (-0.74, -0.24)]
Week 12		123	13.0 (7.39)			122	9.2 (5.72)		
Week 12 chg		123	-8.0 (8.26)	-7.91 (0.56)		122	-12.4 (6.20)	-11.78 (0.56)	-3.88 (-5.43, -2.33) <.001 [-0.53 (-0.79, -0.28)]
Week 16		120	13.0 (7.69)			116	9.1 (5.58)		
Week 16 chg		120	-8.0 (8.09)	-8.08 (0.56)		116	-12.2 (6.39)	-11.81 (0.56)	-3.73 (-5.30, -2.17) <.001 [-0.51 (-0.77, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6306
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.3.423.4.1: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	12.3 (7.64)		109	9.0 (5.60)			
Week 20 chg	102	-8.3 (7.60)	-8.25 (0.58)	109	-12.2 (6.08)	-11.90 (0.57)	-3.65 (-5.25, -2.05) [-0.53 (-0.81, -0.26)]	<.001
Week 26	110	11.8 (7.82)		114	8.2 (5.65)			
Week 26 chg	110	-8.9 (8.23)	-8.77 (0.57)	114	-12.8 (6.59)	-12.64 (0.57)	-3.86 (-5.44, -2.28) [-0.52 (-0.79, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6306
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.423.4.1: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	128 20.9 (5.77)		132	129 21.3 (5.23)		
Week 2		124 15.2 (6.91)			124 13.4 (6.39)		
Week 2 chg		124 -5.9 (6.34)	-5.92 (0.56)		124 -7.9 (5.44)	-7.84 (0.56)	-1.91 (-3.47, -0.36) 0.016 [-0.32 (-0.57, -0.07)]
Week 4		124 13.7 (7.44)			127 11.4 (6.23)		
Week 4 chg		124 -7.2 (7.63)	-7.19 (0.56)		127 -9.9 (5.86)	-9.78 (0.56)	-2.59 (-4.15, -1.04) 0.001 [-0.38 (-0.63, -0.13)]
Week 6		117 13.6 (7.73)			119 10.7 (5.96)		
Week 6 chg		117 -7.2 (8.36)	-7.30 (0.57)		119 -10.8 (6.27)	-10.54 (0.57)	-3.24 (-4.82, -1.66) <.001 [-0.44 (-0.70, -0.18)]
Week 8		121 13.1 (6.87)			120 9.6 (5.76)		
Week 8 chg		121 -7.6 (8.02)	-7.72 (0.56)		120 -11.8 (6.02)	-11.44 (0.56)	-3.72 (-5.29, -2.15) <.001 [-0.52 (-0.78, -0.27)]
Week 12		118 13.3 (7.32)			116 9.0 (5.69)		
Week 12 chg		118 -7.8 (8.37)	-7.79 (0.57)		116 -12.6 (6.13)	-12.00 (0.57)	-4.20 (-5.78, -2.62) <.001 [-0.57 (-0.83, -0.31)]
Week 16		114 13.1 (7.59)			110 8.8 (5.43)		
Week 16 chg		114 -8.0 (8.19)	-8.02 (0.57)		110 -12.4 (6.27)	-12.03 (0.58)	-4.01 (-5.60, -2.42) <.001 [-0.55 (-0.82, -0.28)]
Week 20		98 12.6 (7.67)			104 8.9 (5.69)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6306
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.423.4.1: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	98	-8.2 (7.70)	-8.26 (0.59)	104	-12.3 (6.13)	-11.99 (0.58)	-3.73 (-5.36, -2.09) [-0.54 (-0.82, -0.26)]	<.001
Week 26	106	12.2 (7.77)		108	8.1 (5.67)			
Week 26 chg	106	-8.7 (8.32)	-8.67 (0.58)	108	-13.0 (6.61)	-12.80 (0.58)	-4.12 (-5.73, -2.51) [-0.55 (-0.82, -0.28)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6306
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.423.4.1: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 19.3 (4.59)		6	6 21.3 (1.86)		
Week 2		6 12.7 (7.03)			6 16.8 (3.37)		
Week 2 chg		6 -6.7 (5.54)	-6.34 (2.73)		6 -4.5 (4.23)	-4.56 (2.77)	1.78 (-6.76, 10.31) 0.664 [0.36 (-0.78, 1.50)]
Week 4		6 14.2 (8.47)			6 16.7 (6.15)		
Week 4 chg		6 -5.2 (6.11)	-4.86 (2.73)		6 -4.7 (7.84)	-4.69 (2.77)	0.17 (-8.37, 8.71) 0.967 [0.02 (-1.11, 1.16)]
Week 6		6 12.7 (9.99)			5 14.4 (4.98)		
Week 6 chg		6 -6.7 (7.28)	-5.91 (2.73)		5 -7.2 (5.89)	-7.74 (2.90)	-1.83 (-10.5, 6.87) 0.662 [-0.27 (-1.47, 0.92)]
Week 8		6 12.5 (10.48)			6 15.3 (3.61)		
Week 8 chg		6 -6.8 (6.82)	-5.94 (2.73)		6 -6.0 (5.40)	-6.93 (2.77)	-0.98 (-9.52, 7.56) 0.810 [-0.16 (-1.29, 0.97)]
Week 12		5 7.0 (7.11)			6 13.3 (5.09)		
Week 12 chg		5 -11.8 (3.56)	-9.61 (2.90)		6 -8.0 (6.48)	-8.41 (2.77)	1.20 (-7.58, 9.97) 0.777 [0.22 (-0.97, 1.41)]
Week 16		6 10.5 (9.91)			6 13.3 (6.98)		
Week 16 chg		6 -8.8 (6.49)	-7.99 (2.73)		6 -8.0 (7.80)	-8.85 (2.77)	-0.85 (-9.39, 7.69) 0.835 [-0.12 (-1.25, 1.01)]
Week 20		4 7.0 (5.10)			5 10.4 (3.36)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6306
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.3.423.4.1: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 20 chg		4 -9.8 (4.86)	-7.28 (4.10)		5 -11.0 (5.15)	-10.91 (3.03)	-3.63 (-15.1, 7.88) 0.527 [-0.72 (-2.08, 0.63)]
Week 26		4 3.8 (4.50)			6 11.5 (4.37)		
Week 26 chg		4 -13.0 (3.74)	-10.16 (4.10)		6 -9.8 (5.71)	-10.31 (2.90)	-0.15 (-11.5, 11.18) 0.979 [-0.03 (-1.29, 1.24)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6306
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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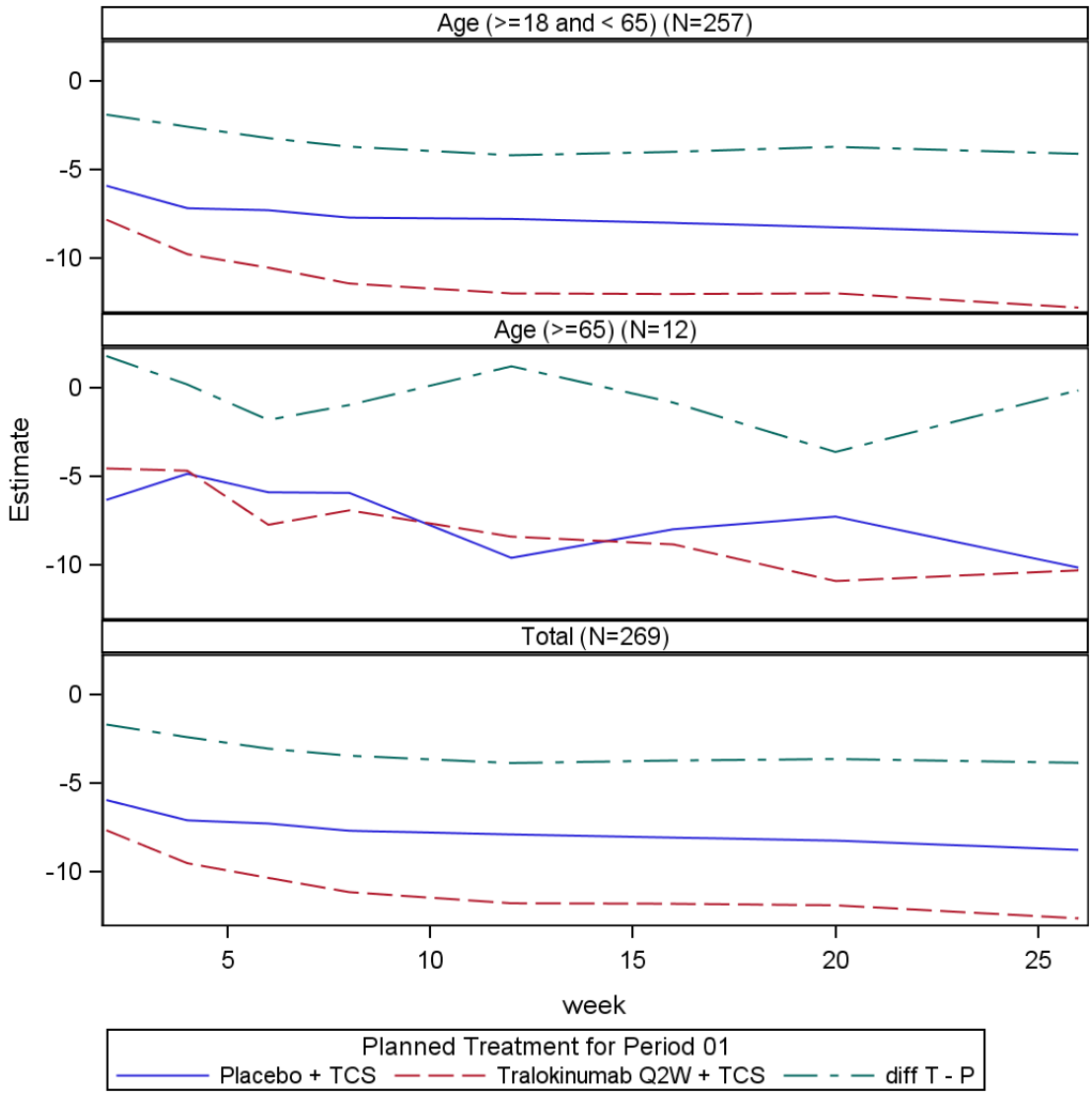
Figure 1.3.423.4.2: Total, Age group, change in POEM, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.3.428.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss								
Total								
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)			
Week 2		137 4.3 (2.75)			138 3.8 (2.71)			
Week 2 chg		137 -2.4 (2.99)	-2.41 (0.22)		138 -2.8 (2.87)	-2.87 (0.22)	-0.45 (-1.08, 0.17)	0.153
							[-0.16 (-0.39, 0.08)]	
Week 4		134 3.4 (2.75)			137 2.9 (2.68)			
Week 4 chg		134 -3.3 (3.29)	-3.23 (0.23)		137 -3.8 (2.99)	-3.80 (0.22)	-0.58 (-1.20, 0.05)	0.071
							[-0.18 (-0.42, 0.06)]	
Week 6		132 3.5 (2.88)			134 2.6 (2.58)			
Week 6 chg		132 -3.2 (3.30)	-3.15 (0.23)		134 -4.1 (2.81)	-4.07 (0.23)	-0.92 (-1.55, -0.29)	0.004
							[-0.30 (-0.54, -0.06)]	
Week 8		133 3.2 (2.69)			130 2.3 (2.47)			
Week 8 chg		133 -3.6 (3.29)	-3.50 (0.23)		130 -4.4 (2.91)	-4.34 (0.23)	-0.84 (-1.47, -0.21)	0.009
							[-0.27 (-0.51, -0.03)]	
Week 10		131 3.0 (2.78)			130 2.2 (2.56)			
Week 10 chg		131 -3.8 (3.38)	-3.65 (0.23)		130 -4.5 (2.93)	-4.46 (0.23)	-0.81 (-1.44, -0.18)	0.012
							[-0.26 (-0.50, -0.01)]	
Week 12		128 2.9 (2.68)			128 2.1 (2.48)			
Week 12 chg		128 -3.9 (3.37)	-3.73 (0.23)		128 -4.6 (2.96)	-4.55 (0.23)	-0.83 (-1.46, -0.19)	0.011
							[-0.26 (-0.51, -0.01)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0447
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.428.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	2.8 (2.94)		127	2.3 (2.60)		
Week 14 chg	126	-4.0 (3.48)	-3.88 (0.23)	127	-4.4 (3.07)	-4.33 (0.23)	-0.45 (-1.09, 0.18) 0.161 [-0.14 (-0.38, 0.11)]
Week 16	124	2.7 (2.77)		123	1.9 (2.39)		
Week 16 chg	124	-4.1 (3.25)	-3.93 (0.23)	123	-4.7 (2.92)	-4.64 (0.23)	-0.72 (-1.36, -0.08) 0.027 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0447
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.428.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)										
Baseline	131	131	6.7 (2.22)		132	132	6.7 (2.34)			
Week 2		131	4.4 (2.76)			132	3.8 (2.73)			
Week 2 chg		131	-2.4 (2.98)	-2.37 (0.23)		132	-2.9 (2.89)	-2.92 (0.23)	-0.56 (-1.19, 0.08) [-0.19 (-0.43, 0.05)]	0.085
Week 4		128	3.5 (2.76)			131	2.8 (2.68)			
Week 4 chg		128	-3.3 (3.34)	-3.19 (0.23)		131	-3.9 (2.95)	-3.90 (0.23)	-0.70 (-1.34, -0.07) [-0.22 (-0.47, 0.02)]	0.030
Week 6		126	3.5 (2.89)			128	2.5 (2.58)			
Week 6 chg		126	-3.2 (3.36)	-3.17 (0.23)		128	-4.2 (2.79)	-4.14 (0.23)	-0.98 (-1.62, -0.34) [-0.32 (-0.56, -0.07)]	0.003
Week 8		127	3.2 (2.66)			124	2.2 (2.48)			
Week 8 chg		127	-3.6 (3.34)	-3.55 (0.23)		124	-4.5 (2.84)	-4.44 (0.23)	-0.89 (-1.53, -0.25) [-0.29 (-0.54, -0.04)]	0.007
Week 10		125	3.1 (2.82)			124	2.1 (2.45)			
Week 10 chg		125	-3.7 (3.42)	-3.64 (0.23)		124	-4.6 (2.76)	-4.61 (0.23)	-0.97 (-1.61, -0.33) [-0.31 (-0.56, -0.06)]	0.003
Week 12		123	2.9 (2.66)			122	2.0 (2.42)			
Week 12 chg		123	-3.9 (3.40)	-3.75 (0.23)		122	-4.8 (2.81)	-4.71 (0.23)	-0.96 (-1.61, -0.32) [-0.31 (-0.56, -0.06)]	0.003
Week 14		120	2.7 (2.93)			121	2.2 (2.60)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0447
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.428.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	120	-4.0 (3.52)	-3.91 (0.23)	121	-4.5 (3.00)	-4.45 (0.23)	-0.54 (-1.18, 0.11) [-0.16 (-0.42, 0.09)]	0.103
Week 16	118	2.7 (2.74)		117	1.8 (2.38)			
Week 16 chg	118	-4.1 (3.27)	-3.96 (0.23)	117	-4.8 (2.79)	-4.78 (0.23)	-0.81 (-1.46, -0.17) [-0.27 (-0.52, -0.01)]	0.014

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0447
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.428.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 7.1 (1.94)		6	6 5.3 (2.64)		
Week 2		6 3.1 (2.47)			6 4.1 (2.62)		
Week 2 chg		6 -3.9 (2.97)	-3.29 (1.06)		6 -1.1 (1.35)	-1.76 (1.05)	1.53 (-1.80, 4.87) 0.349 [0.67 (-0.50, 1.83)]
Week 4		6 2.5 (2.36)			6 4.1 (2.58)		
Week 4 chg		6 -4.6 (1.93)	-3.92 (1.06)		6 -1.2 (2.73)	-1.84 (1.05)	2.08 (-1.26, 5.41) 0.209 [0.88 (-0.31, 2.06)]
Week 6		6 3.8 (2.96)			6 3.4 (2.61)		
Week 6 chg		6 -3.3 (1.92)	-2.82 (1.06)		6 -1.9 (2.47)	-2.37 (1.05)	0.45 (-2.88, 3.79) 0.779 [0.20 (-0.93, 1.34)]
Week 8		6 3.9 (3.42)			6 3.8 (1.82)		
Week 8 chg		6 -3.2 (2.31)	-2.39 (1.06)		6 -1.5 (3.14)	-2.24 (1.05)	0.15 (-3.18, 3.49) 0.924 [0.06 (-1.08, 1.19)]
Week 10		6 2.5 (2.04)			6 4.6 (3.73)		
Week 10 chg		6 -4.6 (2.27)	-3.69 (1.06)		6 -0.7 (3.93)	-1.54 (1.05)	2.16 (-1.18, 5.49) 0.192 [0.67 (-0.49, 1.84)]
Week 12		5 2.7 (3.36)			6 4.8 (2.37)		
Week 12 chg		5 -3.9 (3.01)	-3.03 (1.10)		6 -0.5 (3.43)	-1.37 (1.05)	1.67 (-1.70, 5.03) 0.314 [0.51 (-0.69, 1.72)]
Week 14		6 3.3 (3.48)			6 4.2 (1.67)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0447
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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.

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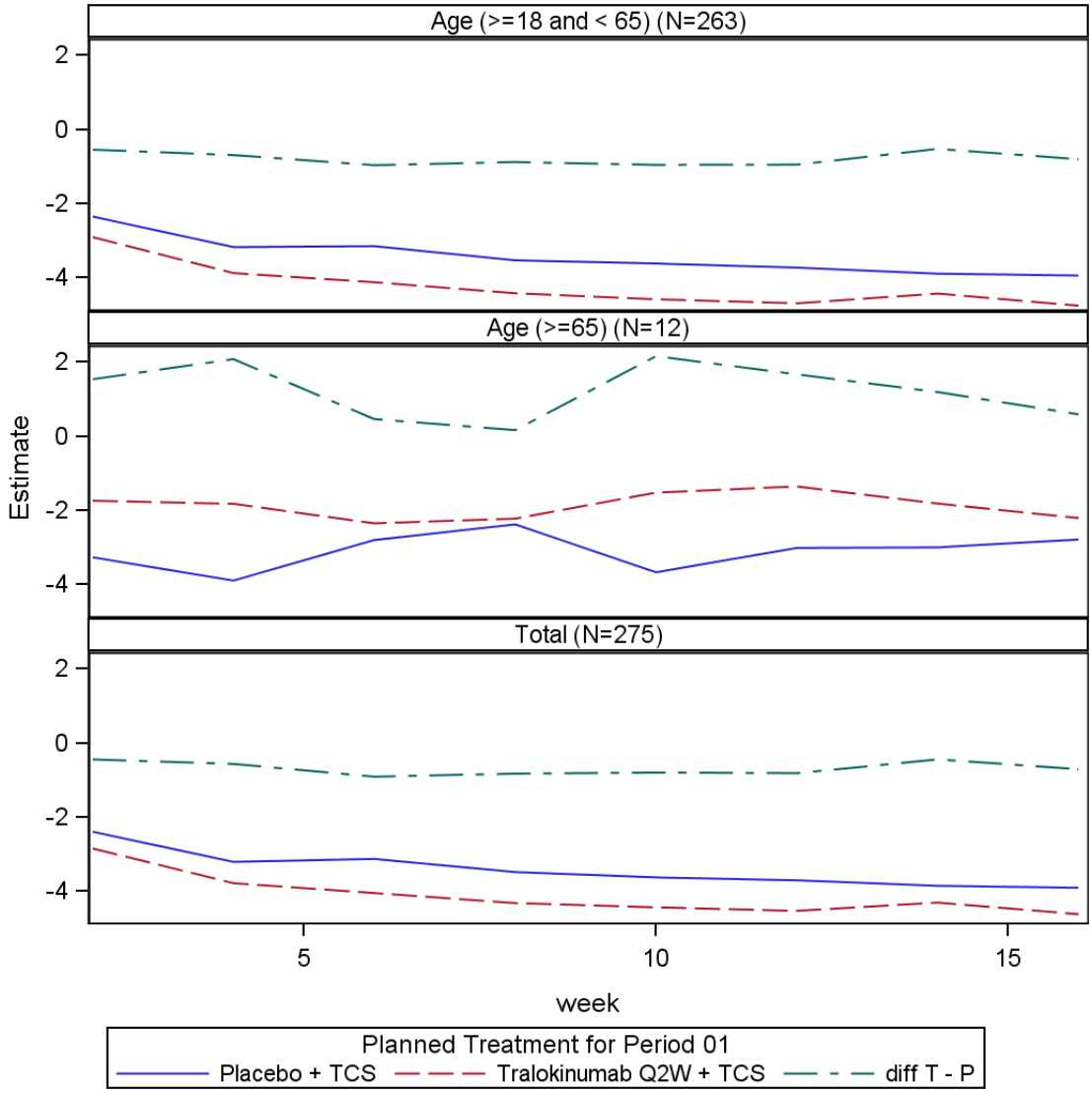
Table 1.3.428.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	6	-3.8 (2.76)	-3.02 (1.06)	6	-1.1 (2.85)	-1.83 (1.05)	1.18 (-2.15, 4.52) [0.42 (-0.72, 1.57)]	0.467
Week 16	6	3.2 (3.57)		6	4.1 (1.69)			
Week 16 chg	6	-3.9 (3.30)	-2.81 (1.06)	6	-1.2 (3.51)	-2.22 (1.05)	0.58 (-2.75, 3.92) [0.17 (-0.96, 1.30)]	0.719

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0447
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.428.4.2: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.3.429.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.80 (1.50)		133	17.3 (19.49)	18.41 (1.49)	2.61 (-1.55, 6.77) 0.219 [0.13 (-0.12, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.37 (1.51)		126	18.4 (21.17)	19.36 (1.51)	2.99 (-1.23, 7.20) 0.165 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.37 (1.53)		122	18.7 (21.48)	19.47 (1.53)	2.11 (-2.15, 6.37) 0.332 [0.09 (-0.16, 0.35)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.72 (1.54)		116	17.7 (22.49)	19.74 (1.55)	5.02 (0.71, 9.33) 0.022 [0.20 (-0.05, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0094
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.429.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)									
Baseline	131	128	52.2 (22.17)		132	129	56.4 (20.17)		
Week 4		125	69.4 (17.83)			127	74.0 (16.79)		
Week 4 chg		125	17.4 (22.33)	15.80 (1.54)		127	17.7 (19.72)	18.87 (1.52)	3.06 (-1.20, 7.33) 0.158 [0.15 (-0.10, 0.39)]
Week 8		121	71.0 (18.95)			120	75.4 (16.33)		
Week 8 chg		121	18.5 (25.36)	16.52 (1.55)		120	19.0 (21.52)	19.85 (1.55)	3.34 (-0.98, 7.65) 0.129 [0.14 (-0.11, 0.39)]
Week 12		118	70.8 (19.31)			116	75.9 (15.99)		
Week 12 chg		118	18.9 (23.19)	17.22 (1.56)		116	19.5 (21.73)	20.17 (1.57)	2.95 (-1.40, 7.31) 0.184 [0.13 (-0.13, 0.39)]
Week 16		114	69.9 (21.40)			110	76.5 (16.66)		
Week 16 chg		114	17.8 (25.98)	15.74 (1.57)		110	18.6 (22.57)	20.63 (1.59)	4.89 (0.48, 9.30) 0.030 [0.20 (-0.06, 0.46)]

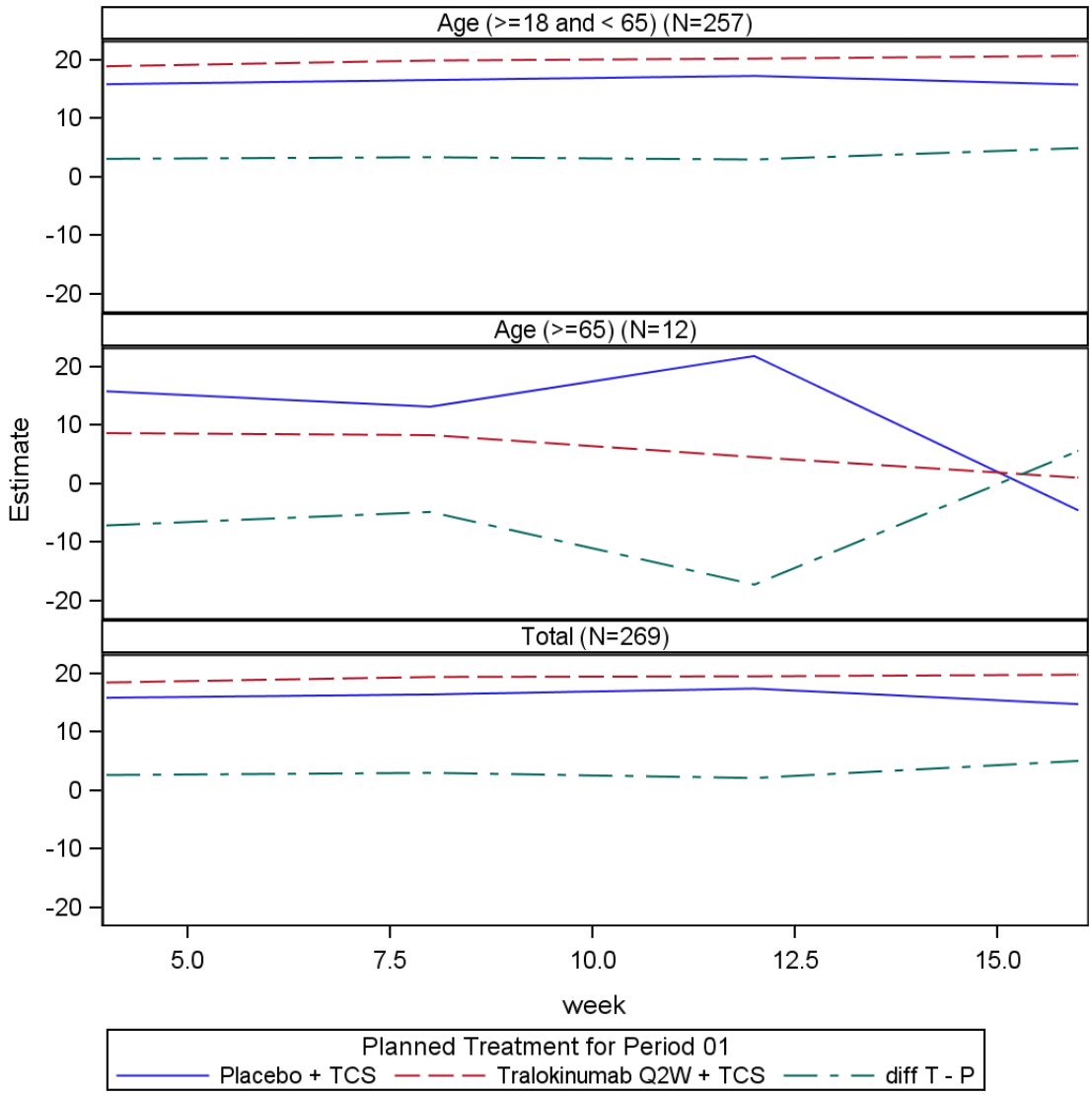
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0094
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.429.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 58.0 (17.92)		6	6 60.3 (13.52)		
Week 4		6 73.8 (12.59)			6 68.8 (16.14)		
Week 4 chg		6 15.8 (6.24)	15.75 (6.64)		6 8.5 (11.71)	8.61 (6.64)	-7.14 (-26.6, 12.33) 0.459 [-0.76 (-1.93, 0.41)]
Week 8		6 71.5 (15.06)			6 68.2 (13.56)		
Week 8 chg		6 13.5 (19.92)	13.12 (6.64)		6 7.8 (6.55)	8.27 (6.64)	-4.84 (-24.3, 14.63) 0.615 [-0.33 (-1.47, 0.81)]
Week 12		5 79.6 (18.45)			6 64.5 (10.89)		
Week 12 chg		5 22.4 (19.76)	21.77 (7.41)		6 4.2 (6.08)	4.52 (6.64)	-17.25 (-37.9, 3.46) 0.099 [-1.24 (-2.53, 0.06)]
Week 16		6 54.2 (26.43)			6 60.5 (17.54)		
Week 16 chg		6 -3.8 (35.11)	-4.58 (6.64)		6 0.2 (11.57)	1.01 (6.64)	5.59 (-13.9, 25.06) 0.562 [0.21 (-0.92, 1.35)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0094
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.429.4.2: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.3.430.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.83 (1.52)		133	17.3 (19.49)	18.45 (1.50)	2.62 (-1.59, 6.82) 0.222 [0.13 (-0.11, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.39 (1.53)		126	18.4 (21.17)	19.38 (1.53)	2.99 (-1.26, 7.24) 0.168 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.49 (1.54)		122	18.7 (21.48)	19.49 (1.54)	1.99 (-2.30, 6.29) 0.362 [0.09 (-0.16, 0.34)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.83 (1.55)		116	17.7 (22.49)	19.65 (1.57)	4.82 (0.48, 9.16) 0.030 [0.19 (-0.06, 0.45)]
Week 20		103	72.7 (20.07)			108	77.3 (14.52)		
Week 20 chg		103	19.3 (25.56)	17.99 (1.61)		108	21.6 (20.57)	21.18 (1.59)	3.20 (-1.26, 7.65) 0.159 [0.14 (-0.13, 0.41)]
Week 26		113	72.4 (20.84)			116	76.4 (17.02)		
Week 26 chg		113	20.5 (25.83)	17.77 (1.58)		116	19.5 (21.18)	20.31 (1.56)	2.53 (-1.84, 6.90) 0.256 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0080
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.430.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)									
Baseline	131	128	52.2 (22.17)		132	129	56.4 (20.17)		
Week 4		125	69.4 (17.83)			127	74.0 (16.79)		
Week 4 chg		125	17.4 (22.33)	15.83 (1.55)		127	17.7 (19.72)	18.91 (1.54)	3.08 (-1.22, 7.39) 0.160 [0.15 (-0.10, 0.39)]
Week 8		121	71.0 (18.95)			120	75.4 (16.33)		
Week 8 chg		121	18.5 (25.36)	16.53 (1.56)		120	19.0 (21.52)	19.88 (1.57)	3.35 (-1.01, 7.71) 0.131 [0.14 (-0.11, 0.40)]
Week 12		118	70.8 (19.31)			116	75.9 (15.99)		
Week 12 chg		118	18.9 (23.19)	17.35 (1.57)		116	19.5 (21.73)	20.19 (1.58)	2.84 (-1.55, 7.23) 0.204 [0.13 (-0.13, 0.38)]
Week 16		114	69.9 (21.40)			110	76.5 (16.66)		
Week 16 chg		114	17.8 (25.98)	15.85 (1.59)		110	18.6 (22.57)	20.54 (1.60)	4.69 (0.24, 9.13) 0.039 [0.19 (-0.07, 0.45)]
Week 20		99	73.2 (19.97)			103	78.1 (14.17)		
Week 20 chg		99	20.0 (24.91)	18.78 (1.64)		103	22.4 (20.62)	21.95 (1.62)	3.17 (-1.38, 7.71) 0.172 [0.14 (-0.14, 0.41)]
Week 26		108	72.3 (21.09)			110	76.9 (17.22)		
Week 26 chg		108	20.8 (25.87)	17.96 (1.61)		110	20.2 (21.39)	20.91 (1.60)	2.95 (-1.53, 7.42) 0.196 [0.12 (-0.14, 0.39)]

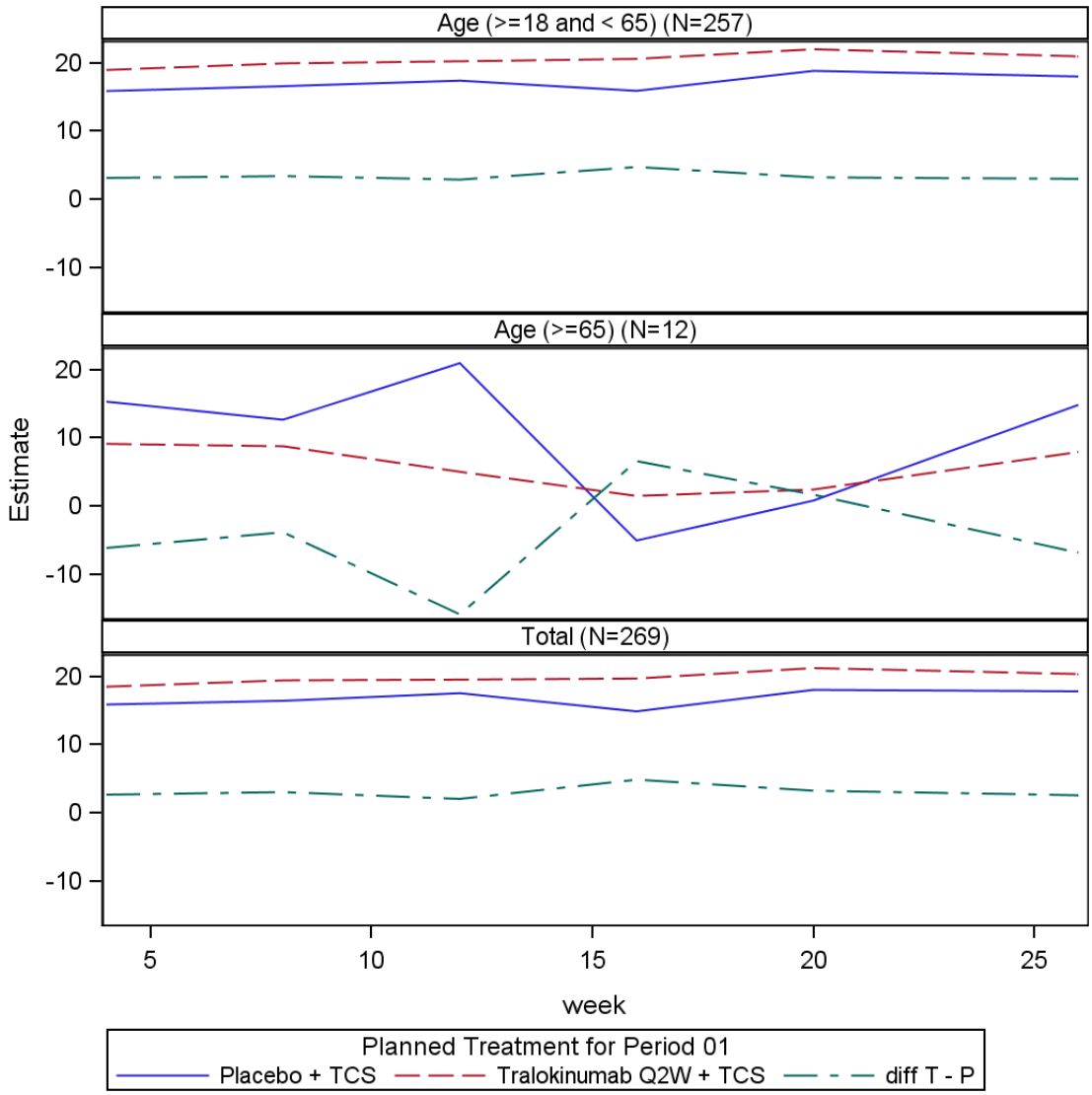
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0080
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.430.4.1: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 58.0 (17.92)		6	6 60.3 (13.52)		
Week 4		6 73.8 (12.59)			6 68.8 (16.14)		
Week 4 chg		6 15.8 (6.24)	15.26 (6.54)		6 8.5 (11.71)	9.07 (6.54)	-6.19 (-25.2, 12.81) 0.513 [-0.66 (-1.82, 0.50)]
Week 8		6 71.5 (15.06)			6 68.2 (13.56)		
Week 8 chg		6 13.5 (19.92)	12.61 (6.54)		6 7.8 (6.55)	8.72 (6.54)	-3.89 (-22.9, 15.10) 0.680 [-0.26 (-1.40, 0.87)]
Week 12		5 79.6 (18.45)			6 64.5 (10.89)		
Week 12 chg		5 22.4 (19.76)	20.91 (7.22)		6 4.2 (6.08)	4.98 (6.54)	-15.94 (-36.0, 4.10) 0.116 [-1.14 (-2.42, 0.14)]
Week 16		6 54.2 (26.43)			6 60.5 (17.54)		
Week 16 chg		6 -3.8 (35.11)	-5.10 (6.54)		6 0.2 (11.57)	1.44 (6.54)	6.54 (-12.5, 25.54) 0.489 [0.25 (-0.89, 1.39)]
Week 20		4 60.8 (21.69)			5 61.2 (13.31)		
Week 20 chg		4 0.5 (38.02)	0.75 (8.10)		5 5.2 (10.80)	2.38 (7.22)	1.63 (-20.7, 23.95) 0.884 [0.06 (-1.25, 1.38)]
Week 26		5 74.6 (16.06)			6 66.8 (8.70)		
Week 26 chg		5 14.0 (26.94)	14.78 (7.21)		6 6.5 (11.26)	7.88 (6.54)	-6.90 (-26.8, 13.04) 0.488 [-0.35 (-1.54, 0.85)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0080
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.3.430.4.2: Total, Age group, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.3.431.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 26		117 2.9 (2.55)			122 2.1 (2.00)		
Week 26 chg		116 -4.0 (2.53)	-3.74 (0.21)		121 -4.1 (2.47)	-4.34 (0.20)	-0.60 (-1.17, -0.03) 0.040 [-0.24 (-0.50, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0610
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.431.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	131	130 6.9 (1.62)		132	131 6.4 (2.09)			
Week 26		112 2.9 (2.56)			116 2.0 (1.98)			
Week 26 chg		111 -4.0 (2.57)	-3.78 (0.21)		115 -4.3 (2.36)	-4.46 (0.20)	-0.68 (-1.26, -0.10) [-0.28 (-0.54, -0.01)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0610
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.431.4.1: Total, Age group, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 7.0 (2.34)		6	6 5.0 (2.30)		
Week 26		5 2.7 (2.52)			6 3.7 (1.97)		
Week 26 chg		5 -3.8 (1.73)	-2.39 (1.13)		6 -1.4 (3.17)	-2.24 (0.98)	0.15 (-3.86, 4.17) 0.929 [0.06 (-1.13, 1.24)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0610
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.434.4.1: Total, Age group, SCORAD 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	21 (15.2)	11.7 (5.02;18.46)	4.3 (1.66;10.96)	5.0 (1.80;13.99)	0.0009	0.0046
Placebo + TCS	137	5 (3.6)					
Age (>=18 and < 65)							
Tralokinumab Q2W + TCS	132	21 (15.9)	13.7 (6.96;20.51)	7.1 (2.14;23.19)	8.1 (2.35;27.69)	0.0001	
Placebo + TCS	131	3 (2.3)					
Age (>=65)							
Tralokinumab Q2W + TCS	6	0 (0.0)	-26.3 (-69.1;16.51)	0.0 (Not estimable)	0.0 (Not estimable)	0.1573	
Placebo + TCS	6	2 (33.3)					

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. Treatment policy estimand: Missing values at Week 26 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

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Table 1.3.437.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 26		121 2.5 (2.71)			127 1.6 (2.07)		
Week 26 chg		121 -4.4 (3.09)	-4.30 (0.21)		127 -5.0 (2.78)	-5.09 (0.21)	-0.78 (-1.37, -0.20) 0.009 [-0.27 (-0.52, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0386
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.437.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	131	131 6.7 (2.22)		132	132 6.7 (2.34)			
Week 26		116 2.5 (2.70)			121 1.5 (1.99)			
Week 26 chg		116 -4.4 (3.11)	-4.33 (0.21)		121 -5.1 (2.66)	-5.21 (0.21)	-0.88 (-1.47, -0.29) [-0.31 (-0.56, -0.05)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0386
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.437.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 7.1 (1.94)		6	6 5.3 (2.64)		
Week 26		5 2.5 (3.29)			6 3.4 (2.94)		
Week 26 chg		5 -4.3 (2.84)	-2.37 (1.09)		6 -1.8 (3.57)	-2.94 (0.96)	-0.57 (-4.40, 3.26) 0.728 [-0.17 (-1.36, 1.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0386
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.438.4.1: Total, Age group, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
SCORAD Score								
Total								
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)			
Week 26		121 33.4 (18.31)			127 24.1 (16.65)			
Week 26 chg		121 -37.9 (19.30)	-37.26 (1.53)		127 -45.9 (19.70)	-46.62 (1.50)	-9.36 (-13.6, -5.13) [-0.48 (-0.73, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1614
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.438.4.1: Total, Age group, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	131	131 70.8 (12.81)		132	132 70.3 (12.06)			
Week 26		116 33.6 (17.89)			121 23.6 (15.99)			
Week 26 chg		116 -37.8 (19.03)	-37.25 (1.52)		121 -46.6 (18.91)	-47.20 (1.49)	-9.96 (-14.1, -5.77) [-0.52 (-0.78, -0.27)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1614
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.438.4.1: Total, Age group, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 72.3 (14.77)		6	6 68.4 (12.78)		
Week 26		5 28.4 (28.66)			6 35.4 (26.18)		
Week 26 chg		5 -39.4 (27.39)	-29.30 (12.12)		6 -33.1 (31.43)	-39.34 (10.39)	-10.04 (-51.1, 30.99) 0.571 [-0.34 (-1.53, 0.86)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1614
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.439.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)							
Total							
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)		
Week 26		117 3.9 (2.53)			122 3.0 (1.94)		
Week 26 chg		116 -3.6 (2.55)	-3.47 (0.20)		121 -4.2 (2.13)	-4.31 (0.20)	-0.84 (-1.41, -0.28) 0.004 [-0.36 (-0.62, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0951
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.439.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	131	130 7.5 (1.34)		132	131 7.3 (1.40)			
Week 26		112 3.9 (2.52)			116 2.9 (1.91)			
Week 26 chg		111 -3.6 (2.57)	-3.51 (0.21)		115 -4.4 (2.06)	-4.44 (0.20)	-0.93 (-1.50, -0.35) [-0.40 (-0.66, -0.14)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0951
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.439.4.1: Total, Age group, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 7.2 (2.17)		6	6 5.8 (1.98)		
Week 26		5 3.7 (2.99)			6 4.3 (2.45)		
Week 26 chg		5 -3.0 (2.39)	-2.11 (1.12)		6 -1.6 (1.67)	-2.06 (0.94)	0.05 (-3.87, 3.96) 0.978 [0.02 (-1.16, 1.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0951
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.440.4.1: Total, Age group, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 26		115 11.9 (7.89)			119 8.4 (5.90)			
Week 26 chg		113 -8.7 (8.23)	-8.90 (0.62)		116 -12.7 (6.64)	-12.63 (0.62)	-3.73 (-5.46, -2.00) [-0.50 (-0.76, -0.24)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4734
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.440.4.1: Total, Age group, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	131	128 20.9 (5.77)		132	129 21.3 (5.23)			
Week 26		110 12.1 (7.74)			113 8.2 (5.94)			
Week 26 chg		108 -8.7 (8.25)	-8.84 (0.64)		110 -12.9 (6.67)	-12.81 (0.63)	-3.97 (-5.74, -2.20) [-0.53 (-0.80, -0.26)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4734
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.440.4.1: Total, Age group, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 19.3 (4.59)		6	6 21.3 (1.86)		
Week 26		5 8.4 (11.10)			6 11.5 (4.37)		
Week 26 chg		5 -9.4 (8.68)	-6.35 (3.74)		6 -9.8 (5.71)	-11.60 (3.18)	-5.25 (-18.8, 8.29) 0.380 [-0.73 (-1.96, 0.49)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4734
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.442.4.1: Total, Age group, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 26		115 6.2 (5.20)			119 4.4 (4.42)		
Week 26 chg		113 -10.3 (6.57)	-10.01 (0.42)		118 -11.2 (6.17)	-11.51 (0.41)	-1.50 (-2.66, -0.34) 0.011 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4890
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.442.4.1: Total, Age group, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	131	128 16.5 (6.34)		132	131 16.0 (6.43)			
Week 26		110 6.3 (5.25)			113 4.3 (4.40)			
Week 26 chg		108 -10.5 (6.61)	-10.11 (0.43)		112 -11.4 (6.10)	-11.76 (0.42)	-1.65 (-2.85, -0.45) [-0.26 (-0.53, 0.01)]	0.007

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4890
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.442.4.1: Total, Age group, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 13.7 (6.09)		6	6 12.3 (8.38)		
Week 26		5 4.0 (3.81)			6 5.8 (4.96)		
Week 26 chg		5 -7.6 (5.46)	-6.11 (1.73)		6 -6.5 (6.12)	-7.11 (1.46)	-1.01 (-6.82, 4.81) 0.687 [-0.17 (-1.36, 1.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4890
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.443.4.1: Total, Age group, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score									
Total									
Baseline	137	137	33.8 (13.46)		138	138	32.1 (11.53)		
Week 26		121	9.0 (10.05)			127	5.8 (7.95)		
Week 26 chg		121	-25.4 (13.63)	-24.33 (0.78)		127	-26.3 (12.87)	-27.34 (0.76)	-3.02 (-5.16, -0.87) 0.006 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1322
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.443.4.1: Total, Age group, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	131 33.8 (13.62)		132	132 31.9 (11.55)		
Week 26		116 9.1 (10.06)			121 5.4 (7.15)		
Week 26 chg		116 -25.4 (13.82)	-24.28 (0.76)		121 -26.5 (12.16)	-27.55 (0.74)	-3.27 (-5.37, -1.18) 0.002 [-0.25 (-0.51, 0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1322
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.443.4.1: Total, Age group, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 34.8 (10.31)		6	6 35.5 (11.49)		
Week 26		5 8.1 (11.06)			6 12.7 (17.45)		
Week 26 chg		5 -25.6 (8.93)	-22.28 (7.44)		6 -22.8 (24.64)	-24.76 (6.39)	-2.49 (-27.7, 22.73) 0.817 [-0.13 (-1.32, 1.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1322
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.444.3.1: Total, Age group, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
EASI Score										
Total										
Baseline	126	126	30.4 (12.78)		252	252	28.8 (11.97)			
Week 16		123	14.1 (14.89)			241	8.1 (9.15)			
Week 16 chg		123	-16.0 (14.04)	-15.43 (0.94)		241	-20.7 (12.33)	-20.93 (0.67)	-5.50 (-7.79, -3.22) [-0.43 (-0.64, -0.21)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9670
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.444.3.1: Total, Age group, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	118	118 30.3 (12.85)		236	236 29.0 (11.94)		
Week 16		116 14.0 (14.80)			226 8.1 (9.21)		
Week 16 chg		116 -16.1 (13.80)	-15.56 (0.97)		226 -20.7 (12.25)	-20.99 (0.69)	-5.43 (-7.77, -3.09) <.001 [-0.42 (-0.65, -0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9670
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.444.3.1: Total, Age group, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	8	8 32.0 (12.49)		16	16 26.7 (12.50)		
Week 16		7 15.4 (17.62)			15 7.9 (8.48)		
Week 16 chg		7 -14.9 (18.77)	-13.34 (4.67)		15 -19.4 (13.89)	-20.10 (3.20)	-6.77 (-18.8, 5.23) 0.250 [-0.44 (-1.34, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9670
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.3.445.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.39 (0.22)		138 -2.8 (2.87)	-2.85 (0.22)	-0.46 (-1.07, 0.15) 0.140 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.20 (0.22)		137 -3.8 (2.99)	-3.79 (0.22)	-0.58 (-1.20, 0.03) 0.062 [-0.19 (-0.42, 0.05)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.13 (0.22)		134 -4.1 (2.81)	-4.06 (0.22)	-0.93 (-1.54, -0.31) 0.003 [-0.30 (-0.54, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.47 (0.22)		130 -4.4 (2.91)	-4.33 (0.22)	-0.85 (-1.47, -0.24) 0.007 [-0.27 (-0.52, -0.03)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.62 (0.22)		130 -4.5 (2.93)	-4.44 (0.22)	-0.82 (-1.43, -0.20) 0.009 [-0.26 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.70 (0.22)		128 -4.6 (2.96)	-4.53 (0.22)	-0.83 (-1.45, -0.21) 0.008 [-0.26 (-0.51, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0234
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.3.445.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	2.8 (2.94)		127	2.3 (2.60)		
Week 14 chg	126	-4.0 (3.48)	-3.86 (0.22)	127	-4.4 (3.07)	-4.31 (0.22)	-0.45 (-1.07, 0.17) 0.156 [-0.14 (-0.38, 0.11)]
Week 16	124	2.7 (2.77)		123	1.9 (2.39)		
Week 16 chg	124	-4.1 (3.25)	-3.91 (0.22)	123	-4.7 (2.92)	-4.63 (0.22)	-0.72 (-1.34, -0.10) 0.024 [-0.23 (-0.48, 0.02)]
Week 18	116	2.9 (2.83)		115	1.7 (2.27)		
Week 18 chg	116	-3.9 (3.35)	-3.71 (0.23)	115	-4.8 (2.93)	-4.81 (0.23)	-1.10 (-1.73, -0.47) <.001 [-0.35 (-0.61, -0.09)]
Week 20	107	2.6 (2.71)		117	1.8 (2.37)		
Week 20 chg	107	-4.1 (3.17)	-3.95 (0.23)	117	-4.8 (2.97)	-4.78 (0.23)	-0.83 (-1.46, -0.20) 0.010 [-0.27 (-0.53, -0.01)]
Week 22	112	2.5 (2.71)		114	1.5 (2.00)		
Week 22 chg	112	-4.2 (3.34)	-4.07 (0.23)	114	-5.0 (2.85)	-4.94 (0.23)	-0.87 (-1.51, -0.24) 0.007 [-0.28 (-0.54, -0.02)]
Week 24	112	2.3 (2.55)		117	1.5 (2.05)		
Week 24 chg	112	-4.4 (3.18)	-4.21 (0.23)	117	-5.1 (2.80)	-4.96 (0.23)	-0.76 (-1.39, -0.12) 0.019 [-0.25 (-0.51, 0.01)]
Week 26	118	2.4 (2.70)		125	1.6 (2.07)		
Week 26 chg	118	-4.4 (3.11)	-4.20 (0.23)	125	-5.0 (2.80)	-4.92 (0.22)	-0.72 (-1.35, -0.10) 0.024 [-0.24 (-0.50, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0234
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

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Table 1.3.445.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)										
Baseline	131	131	6.7 (2.22)		132	132	6.7 (2.34)			
Week 2		131	4.4 (2.76)			132	3.8 (2.73)			
Week 2 chg		131	-2.4 (2.98)	-2.36 (0.22)		132	-2.9 (2.89)	-2.92 (0.22)	-0.56 (-1.18, 0.06) [-0.19 (-0.43, 0.05)]	0.076
Week 4		128	3.5 (2.76)			131	2.8 (2.68)			
Week 4 chg		128	-3.3 (3.34)	-3.18 (0.22)		131	-3.9 (2.95)	-3.89 (0.22)	-0.71 (-1.33, -0.09) [-0.23 (-0.47, 0.02)]	0.025
Week 6		126	3.5 (2.89)			128	2.5 (2.58)			
Week 6 chg		126	-3.2 (3.36)	-3.15 (0.22)		128	-4.2 (2.79)	-4.14 (0.22)	-0.98 (-1.60, -0.36) [-0.32 (-0.57, -0.07)]	0.002
Week 8		127	3.2 (2.66)			124	2.2 (2.48)			
Week 8 chg		127	-3.6 (3.34)	-3.53 (0.22)		124	-4.5 (2.84)	-4.43 (0.22)	-0.91 (-1.53, -0.28) [-0.29 (-0.54, -0.04)]	0.005
Week 10		125	3.1 (2.82)			124	2.1 (2.45)			
Week 10 chg		125	-3.7 (3.42)	-3.61 (0.23)		124	-4.6 (2.76)	-4.59 (0.22)	-0.97 (-1.60, -0.35) [-0.31 (-0.56, -0.06)]	0.002
Week 12		123	2.9 (2.66)			122	2.0 (2.42)			
Week 12 chg		123	-3.9 (3.40)	-3.73 (0.23)		122	-4.8 (2.81)	-4.70 (0.23)	-0.97 (-1.59, -0.34) [-0.31 (-0.56, -0.06)]	0.003
Week 14		120	2.7 (2.93)			121	2.2 (2.60)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0234
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

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Table 1.3.445.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	120	-4.0 (3.52)	-3.91 (0.23)	121	-4.5 (3.00)	-4.44 (0.23)	-0.53 (-1.16, 0.10) [-0.16 (-0.42, 0.09)]	0.098
Week 16	118	2.7 (2.74)		117	1.8 (2.38)			
Week 16 chg	118	-4.1 (3.27)	-3.95 (0.23)	117	-4.8 (2.79)	-4.76 (0.23)	-0.81 (-1.45, -0.18) [-0.27 (-0.52, -0.01)]	0.012
Week 18	110	2.9 (2.80)		110	1.6 (2.25)			
Week 18 chg	110	-3.9 (3.39)	-3.75 (0.23)	110	-5.0 (2.79)	-4.94 (0.23)	-1.19 (-1.83, -0.55) [-0.38 (-0.65, -0.12)]	<.001
Week 20	102	2.5 (2.62)		112	1.7 (2.34)			
Week 20 chg	102	-4.2 (3.11)	-4.07 (0.23)	112	-5.0 (2.82)	-4.91 (0.23)	-0.84 (-1.48, -0.20) [-0.28 (-0.55, -0.01)]	0.011
Week 22	108	2.5 (2.73)		109	1.4 (1.96)			
Week 22 chg	108	-4.2 (3.37)	-4.09 (0.23)	109	-5.2 (2.68)	-5.09 (0.23)	-1.00 (-1.64, -0.36) [-0.33 (-0.60, -0.06)]	0.002
Week 24	108	2.3 (2.57)		112	1.4 (1.99)			
Week 24 chg	108	-4.4 (3.21)	-4.21 (0.23)	112	-5.2 (2.62)	-5.09 (0.23)	-0.88 (-1.52, -0.24) [-0.30 (-0.57, -0.04)]	0.007
Week 26	114	2.5 (2.72)		119	1.5 (1.99)			
Week 26 chg	114	-4.4 (3.13)	-4.23 (0.23)	119	-5.1 (2.68)	-5.04 (0.23)	-0.81 (-1.45, -0.18) [-0.28 (-0.54, -0.02)]	0.012

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0234
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.3.445.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 7.1 (1.94)		6	6 5.3 (2.64)		
Week 2		6 3.1 (2.47)			6 4.1 (2.62)		
Week 2 chg		6 -3.9 (2.97)	-3.16 (1.07)		6 -1.1 (1.35)	-1.72 (1.01)	1.44 (-1.81, 4.68) 0.368 [0.62 (-0.54, 1.78)]
Week 4		6 2.5 (2.36)			6 4.1 (2.58)		
Week 4 chg		6 -4.6 (1.93)	-3.77 (1.07)		6 -1.2 (2.73)	-1.79 (1.01)	1.98 (-1.27, 5.23) 0.219 [0.84 (-0.34, 2.02)]
Week 6		6 3.8 (2.96)			6 3.4 (2.61)		
Week 6 chg		6 -3.3 (1.92)	-2.73 (1.07)		6 -1.9 (2.47)	-2.37 (1.01)	0.36 (-2.89, 3.60) 0.821 [0.16 (-0.97, 1.29)]
Week 8		6 3.9 (3.42)			6 3.8 (1.82)		
Week 8 chg		6 -3.2 (2.31)	-2.24 (1.07)		6 -1.5 (3.14)	-2.18 (1.01)	0.06 (-3.19, 3.31) 0.970 [0.02 (-1.11, 1.15)]
Week 10		6 2.5 (2.04)			6 4.6 (3.73)		
Week 10 chg		6 -4.6 (2.27)	-3.51 (1.07)		6 -0.7 (3.93)	-1.45 (1.01)	2.06 (-1.19, 5.31) 0.201 [0.64 (-0.52, 1.80)]
Week 12		5 2.7 (3.36)			6 4.8 (2.37)		
Week 12 chg		5 -3.9 (3.01)	-2.84 (1.10)		6 -0.5 (3.43)	-1.27 (1.01)	1.56 (-1.71, 4.84) 0.332 [0.48 (-0.72, 1.68)]
Week 14		6 3.3 (3.48)			6 4.2 (1.67)		

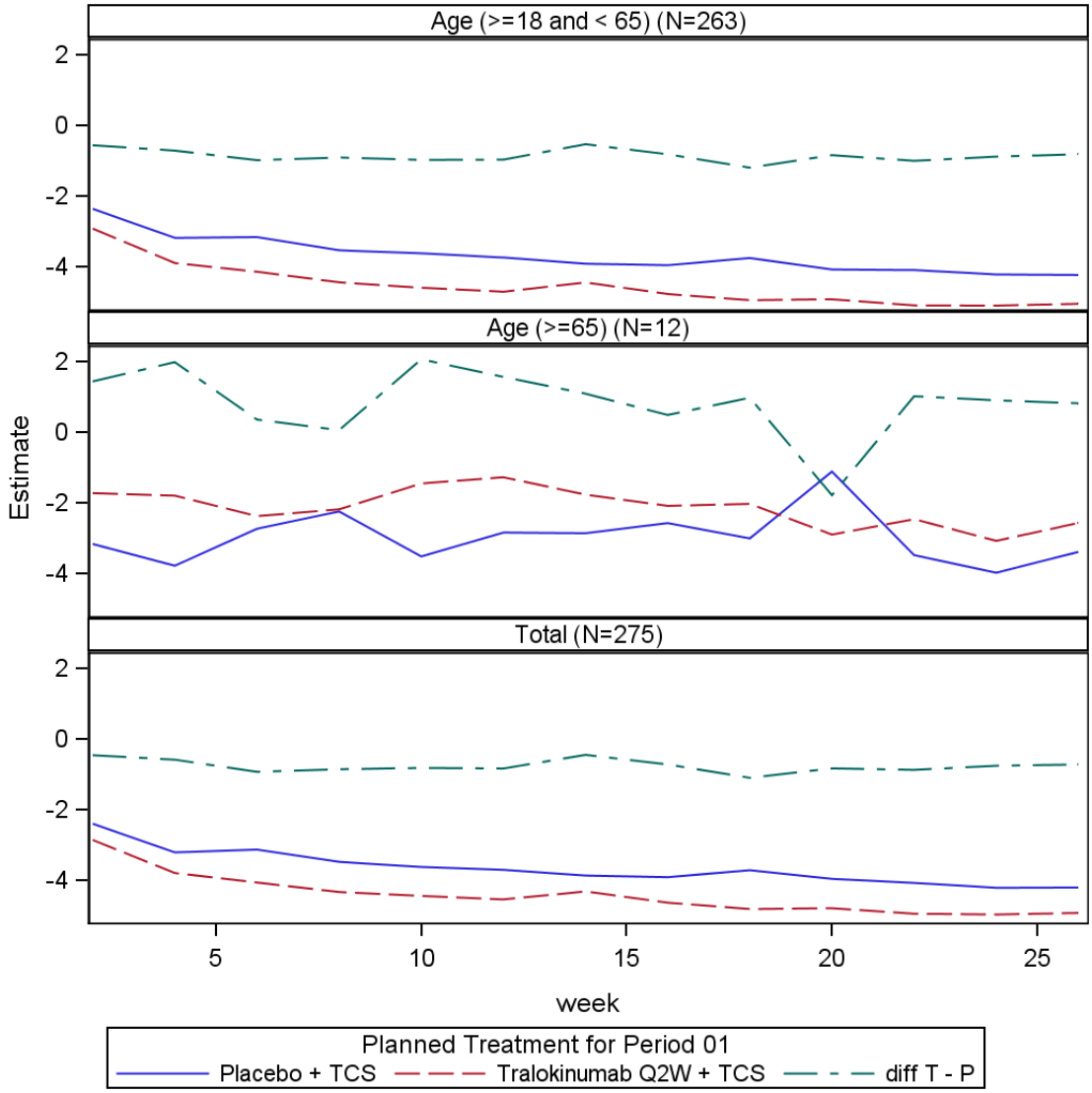
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0234
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.3.445.4.1: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	6	-3.8 (2.76)	-2.85 (1.07)	6	-1.1 (2.85)	-1.77 (1.01)	1.09 (-2.16, 4.34) 0.494 [0.39 (-0.75, 1.53)]
Week 16	6	3.2 (3.57)		6	4.1 (1.69)		
Week 16 chg	6	-3.9 (3.30)	-2.57 (1.07)	6	-1.2 (3.51)	-2.08 (1.01)	0.49 (-2.76, 3.73) 0.759 [0.14 (-0.99, 1.28)]
Week 18	6	3.2 (3.63)		5	3.3 (2.40)		
Week 18 chg	6	-3.9 (2.84)	-3.00 (1.11)	5	-1.1 (3.65)	-2.03 (1.19)	0.98 (-2.72, 4.67) 0.595 [0.30 (-0.89, 1.50)]
Week 20	5	4.2 (4.22)		5	3.2 (2.89)		
Week 20 chg	5	-2.4 (4.15)	-1.11 (1.12)	5	-1.1 (4.15)	-2.89 (1.22)	-1.78 (-5.48, 1.92) 0.335 [-0.43 (-1.68, 0.82)]
Week 22	4	1.0 (1.60)		5	3.5 (1.97)		
Week 22 chg	4	-5.1 (2.72)	-3.47 (1.16)	5	-0.8 (3.36)	-2.46 (1.28)	1.02 (-2.68, 4.72) 0.580 [0.33 (-1.00, 1.65)]
Week 24	4	0.5 (0.63)		5	3.1 (2.85)		
Week 24 chg	4	-5.6 (1.91)	-3.97 (1.16)	5	-1.2 (4.21)	-3.07 (1.28)	0.90 (-2.80, 4.60) 0.624 [0.26 (-1.06, 1.58)]
Week 26	4	1.2 (1.72)		6	3.4 (2.94)		
Week 26 chg	4	-5.0 (2.79)	-3.38 (1.16)	6	-1.8 (3.57)	-2.56 (1.01)	0.82 (-2.50, 4.14) 0.616 [0.25 (-1.02, 1.52)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0234
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.3.445.4.2: Total, Age group, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.3.446.4.1: Total, Age group, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.89 (0.84)		123 -25.9 (12.78)	-26.75 (0.84)	-3.86 (-6.21, -1.51) 0.001 [-0.28 (-0.53, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0024
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.446.4.1: Total, Age group, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)								
Baseline	131	131 33.8 (13.62)		132	132 31.9 (11.55)			
Week 16		118 10.1 (10.37)			117 6.1 (7.17)			
Week 16 chg		118 -24.2 (14.61)	-23.29 (0.78)		117 -26.0 (12.32)	-26.90 (0.79)	-3.61 (-5.80, -1.42) [-0.27 (-0.52, -0.01)]	0.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0024
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.446.4.1: Total, Age group, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 34.8 (10.31)		6	6 35.5 (11.49)		
Week 16		6 20.0 (24.05)			6 12.3 (13.57)		
Week 16 chg		6 -14.7 (19.67)	-10.68 (6.96)		6 -23.2 (21.25)	-27.23 (6.96)	-16.55 (-40.6, 7.50) 0.148 [-0.81 (-1.99, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0024
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.463.4.1: Total, Age group, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary							
Total							
Baseline	137	134 44.5 (8.19)		138	134 44.5 (7.83)		
Week 8		129 50.3 (7.06)			129 51.7 (7.07)		
Week 8 chg		129 5.6 (7.75)	5.69 (0.56)		129 7.4 (7.27)	7.16 (0.56)	1.47 (-0.08, 3.03) 0.063 [0.20 (-0.05, 0.44)]
Week 16		119 50.9 (7.78)			113 52.9 (6.85)		
Week 16 chg		119 6.8 (8.15)	6.49 (0.57)		113 8.0 (7.67)	7.87 (0.58)	1.39 (-0.22, 2.99) 0.090 [0.17 (-0.08, 0.43)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3110
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.463.4.1: Total, Age group, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)									
Baseline	131	128	44.5 (8.33)		132	128	44.5 (7.88)		
Week 8		123	50.3 (7.15)			123	51.8 (7.18)		
Week 8 chg		123	5.6 (7.78)	5.71 (0.57)		123	7.5 (7.39)	7.25 (0.57)	1.54 (-0.06, 3.13) 0.059 [0.20 (-0.05, 0.45)]
Week 16		113	51.1 (7.74)			107	53.1 (6.78)		
Week 16 chg		113	7.0 (8.21)	6.64 (0.59)		107	8.2 (7.79)	8.10 (0.60)	1.46 (-0.19, 3.11) 0.082 [0.18 (-0.08, 0.45)]

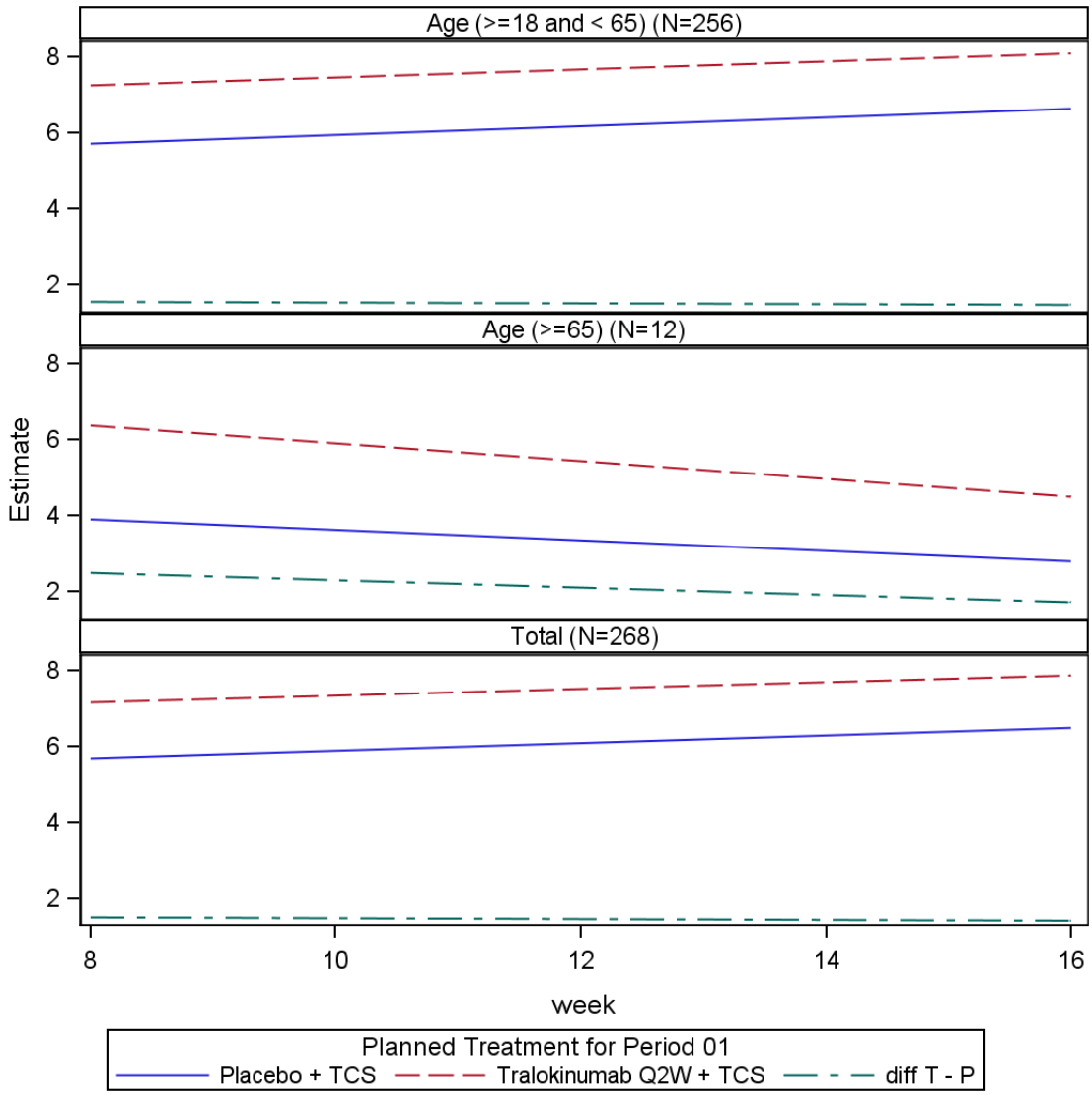
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3110
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.463.4.1: Total, Age group, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 44.2 (4.70)		6	6 45.3 (7.35)		
Week 8		6 49.2 (5.19)			6 50.5 (4.68)		
Week 8 chg		6 5.0 (7.83)	3.89 (2.10)		6 5.3 (3.93)	6.37 (2.10)	2.48 (-4.32, 9.28) 0.436 [0.40 (-0.74, 1.54)]
Week 16		6 47.8 (8.71)			6 49.0 (7.44)		
Week 16 chg		6 3.5 (6.72)	2.79 (2.10)		6 3.7 (2.96)	4.49 (2.10)	1.71 (-5.09, 8.50) 0.589 [0.33 (-0.81, 1.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3110
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.463.4.2: Total, Age group, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, 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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.464.4.1: Total, Age group, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary									
Total									
Baseline	137	134	44.9 (11.42)		138	134	46.3 (9.74)		
Week 8		129	49.6 (10.25)			129	49.7 (9.51)		
Week 8 chg		129	4.4 (7.37)	4.13 (0.64)		129	3.7 (8.69)	3.69 (0.63)	-0.44 (-2.21, 1.33) 0.625 [-0.05 (-0.30, 0.19)]
Week 16		119	49.5 (10.11)			113	49.9 (9.68)		
Week 16 chg		119	4.4 (8.65)	4.08 (0.65)		113	3.4 (8.59)	3.59 (0.66)	-0.50 (-2.32, 1.33) 0.594 [-0.06 (-0.32, 0.20)]
Week 26		110	50.4 (9.75)			112	51.4 (7.72)		
Week 26 chg		110	5.5 (8.68)	4.92 (0.67)		112	4.6 (8.26)	4.50 (0.66)	-0.42 (-2.27, 1.44) 0.660 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7899
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.464.4.1: Total, Age group, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)									
Baseline	131	128	44.5 (11.31)		132	128	46.1 (9.66)		
Week 8		123	49.5 (10.37)			123	49.5 (9.61)		
Week 8 chg		123	4.7 (7.34)	4.39 (0.66)		123	3.7 (8.76)	3.79 (0.66)	-0.59 (-2.42, 1.23) 0.523 [-0.07 (-0.32, 0.18)]
Week 16		113	49.3 (10.09)			107	49.7 (9.73)		
Week 16 chg		113	4.6 (8.62)	4.26 (0.67)		107	3.5 (8.63)	3.65 (0.69)	-0.61 (-2.50, 1.29) 0.529 [-0.07 (-0.33, 0.19)]
Week 26		106	50.2 (9.80)			106	51.2 (7.84)		
Week 26 chg		106	5.6 (8.74)	5.03 (0.69)		106	4.6 (8.19)	4.51 (0.69)	-0.52 (-2.44, 1.40) 0.593 [-0.06 (-0.33, 0.21)]

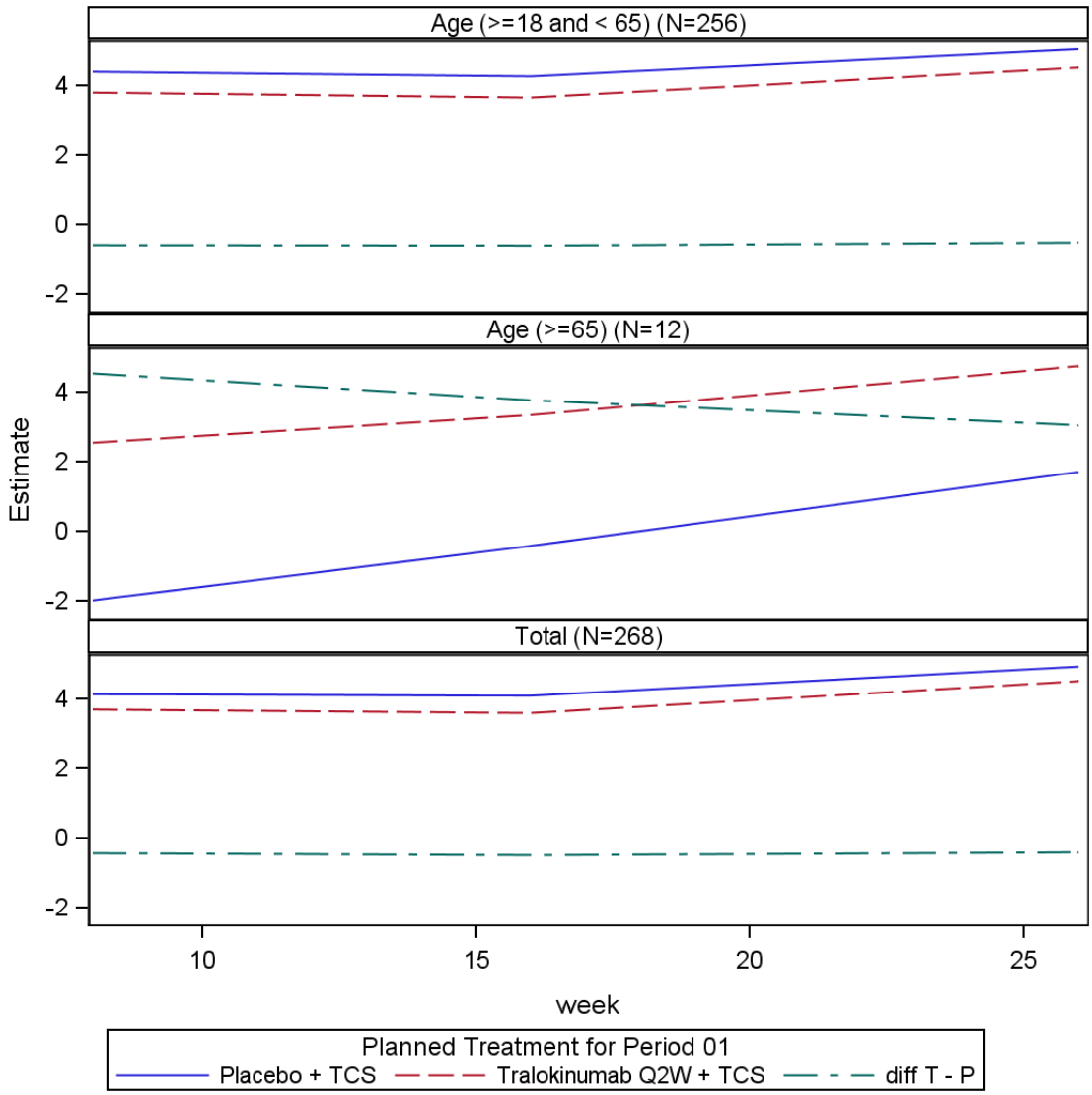
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7899
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.464.4.1: Total, Age group, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=65)								
Baseline	6	6 52.8 (11.80)		6	6 50.0 (11.79)			
Week 8		6 51.0 (8.05)			6 52.3 (7.27)			
Week 8 chg		6 -1.8 (5.22)	-1.99 (2.12)		6 2.3 (7.62)	2.54 (2.12)	4.53 (-1.95, 11.00) [0.69 (-0.47, 1.86)]	0.159
Week 16		6 52.6 (10.87)			6 53.1 (8.91)			
Week 16 chg		6 -0.2 (8.60)	-0.42 (2.12)		6 3.1 (8.60)	3.33 (2.12)	3.76 (-2.72, 10.23) [0.44 (-0.71, 1.58)]	0.239
Week 26		4 54.8 (8.03)			6 54.8 (4.20)			
Week 26 chg		4 1.5 (6.09)	1.70 (2.73)		6 4.9 (10.35)	4.74 (2.13)	3.04 (-4.44, 10.53) [0.34 (-0.94, 1.61)]	0.408

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7899
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.464.4.2: Total, Age group, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.465.4.1: Total, Age group, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary									
Total									
Baseline	137	134	44.5 (8.19)		138	134	44.5 (7.83)		
Week 8		129	50.3 (7.06)			129	51.7 (7.07)		
Week 8 chg		129	5.6 (7.75)	5.70 (0.56)		129	7.4 (7.27)	7.18 (0.56)	1.48 (-0.09, 3.04) 0.064 [0.20 (-0.05, 0.44)]
Week 16		119	50.9 (7.78)			113	52.9 (6.85)		
Week 16 chg		119	6.8 (8.15)	6.57 (0.57)		113	8.0 (7.67)	7.95 (0.58)	1.37 (-0.23, 2.98) 0.093 [0.17 (-0.08, 0.43)]
Week 26		110	50.7 (7.62)			112	52.9 (7.40)		
Week 26 chg		110	6.9 (8.19)	6.11 (0.59)		112	8.2 (7.71)	8.22 (0.58)	2.11 (0.48, 3.74) 0.011 [0.27 (0.00, 0.53)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5437
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.465.4.1: Total, Age group, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)									
Baseline	131	128	44.5 (8.33)		132	128	44.5 (7.88)		
Week 8		123	50.3 (7.15)			123	51.8 (7.18)		
Week 8 chg		123	5.6 (7.78)	5.73 (0.58)		123	7.5 (7.39)	7.27 (0.58)	1.54 (-0.07, 3.14) 0.060 [0.20 (-0.05, 0.45)]
Week 16		113	51.1 (7.74)			107	53.1 (6.78)		
Week 16 chg		113	7.0 (8.21)	6.72 (0.59)		107	8.2 (7.79)	8.17 (0.60)	1.45 (-0.20, 3.10) 0.086 [0.18 (-0.08, 0.45)]
Week 26		106	50.8 (7.71)			106	53.0 (7.48)		
Week 26 chg		106	6.8 (8.14)	6.19 (0.60)		106	8.4 (7.82)	8.36 (0.60)	2.18 (0.51, 3.84) 0.011 [0.27 (0.00, 0.54)]

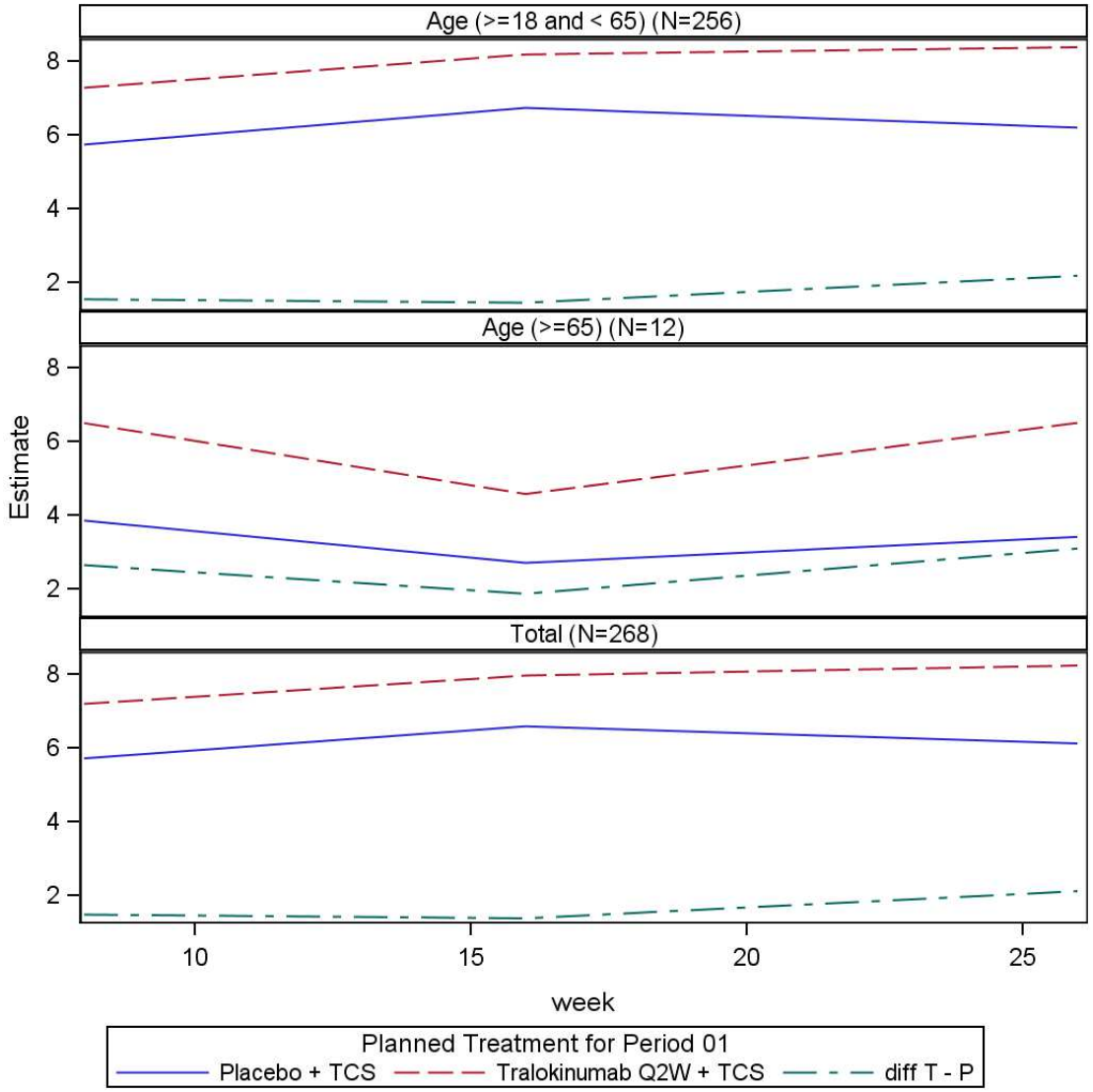
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5437
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.465.4.1: Total, Age group, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 44.2 (4.70)		6	6 45.3 (7.35)		
Week 8		6 49.2 (5.19)			6 50.5 (4.68)		
Week 8 chg		6 5.0 (7.83)	3.85 (2.11)		6 5.3 (3.93)	6.49 (2.11)	2.64 (-3.71, 8.99) 0.395 [0.43 (-0.72, 1.57)]
Week 16		6 47.8 (8.71)			6 49.0 (7.44)		
Week 16 chg		6 3.5 (6.72)	2.70 (2.11)		6 3.7 (2.96)	4.56 (2.11)	1.86 (-4.49, 8.22) 0.546 [0.36 (-0.78, 1.50)]
Week 26		4 50.5 (5.51)			6 50.5 (5.83)		
Week 26 chg		4 7.0 (10.73)	3.40 (2.72)		6 5.2 (5.02)	6.49 (2.11)	3.09 (-4.28, 10.45) 0.393 [0.40 (-0.87, 1.68)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5437
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.465.4.2: Total, Age group, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.466.4.1: Total, Age group, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary									
Total									
Baseline	137	134	44.9 (11.42)		138	134	46.3 (9.74)		
Week 8		129	49.6 (10.25)			129	49.7 (9.51)		
Week 8 chg		129	4.4 (7.37)	4.14 (0.65)		129	3.7 (8.69)	3.66 (0.65)	-0.47 (-2.28, 1.34) 0.607 [-0.06 (-0.30, 0.19)]
Week 16		119	49.5 (10.11)			113	49.9 (9.68)		
Week 16 chg		119	4.4 (8.65)	4.09 (0.67)		113	3.4 (8.59)	3.63 (0.68)	-0.46 (-2.34, 1.42) 0.629 [-0.05 (-0.31, 0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8112
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.466.4.1: Total, Age group, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Age (>=18 and < 65)												
Baseline	131	128	44.5 (11.31)			132	128	46.1 (9.66)				
Week 8		123	49.5 (10.37)				123	49.5 (9.61)				
Week 8 chg		123	4.7 (7.34)	4.40	(0.67)		123	3.7 (8.76)	3.77	(0.67)	-0.63 (-2.50, 1.24) [-0.08 (-0.33, 0.17)]	0.508
Week 16		113	49.3 (10.09)				107	49.7 (9.73)				
Week 16 chg		113	4.6 (8.62)	4.26	(0.69)		107	3.5 (8.63)	3.69	(0.70)	-0.58 (-2.52, 1.37) [-0.07 (-0.33, 0.20)]	0.561

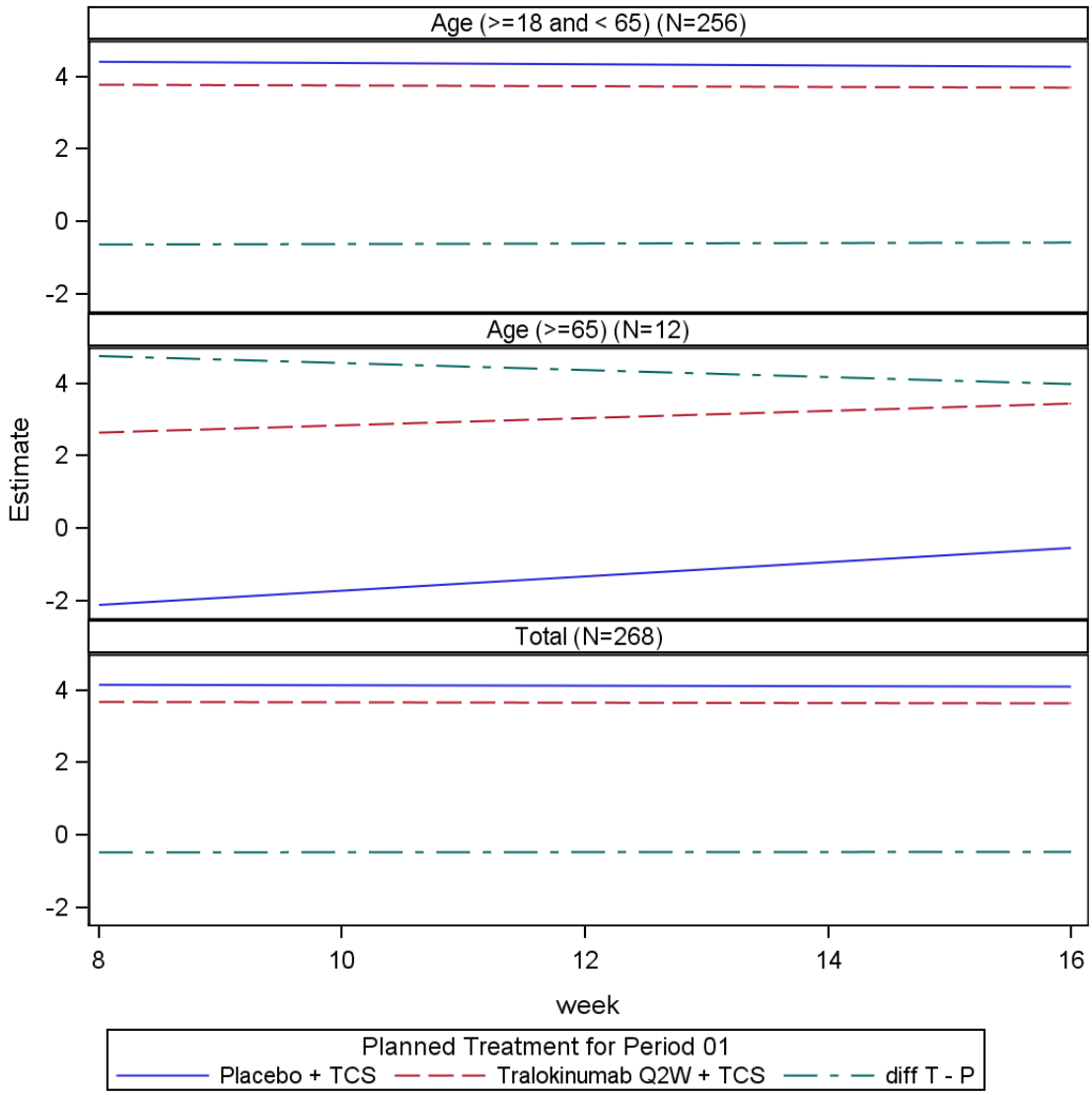
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8112
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.466.4.1: Total, Age group, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 52.8 (11.80)		6	6 50.0 (11.79)		
Week 8		6 51.0 (8.05)			6 52.3 (7.27)		
Week 8 chg		6 -1.8 (5.22)	-2.11 (2.34)		6 2.3 (7.62)	2.63 (2.34)	4.74 (-2.55, 12.03) 0.185 [0.73 (-0.44, 1.89)]
Week 16		6 52.6 (10.87)			6 53.1 (8.91)		
Week 16 chg		6 -0.2 (8.60)	-0.54 (2.34)		6 3.1 (8.60)	3.43 (2.34)	3.97 (-3.32, 11.26) 0.263 [0.46 (-0.68, 1.61)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8112
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.466.4.2: Total, Age group, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, 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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.3.469.4.1: Total, Age group, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 26		115	50.7 (9.70)				118	51.1 (7.88)			
Week 26 chg		113	5.6 (8.87)	5.14	(0.66)		114	4.4 (8.31)	4.80	(0.66)	-0.34 (-2.18, 1.50) 0.715 [-0.04 (-0.30, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9160
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.469.4.1: Total, Age group, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	128 44.5 (11.31)		132	128 46.1 (9.66)		
Week 26		110 50.4 (9.73)			112 50.9 (7.99)		
Week 26 chg		108 5.8 (8.96)	5.27 (0.69)		108 4.4 (8.24)	4.86 (0.68)	-0.40 (-2.32, 1.51) 0.678 [-0.05 (-0.31, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9160
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.469.4.1: Total, Age group, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 52.8 (11.80)		6	6 50.0 (11.79)		
Week 26		5 56.3 (7.74)			6 54.8 (4.20)		
Week 26 chg		5 1.1 (5.35)	3.23 (2.33)		6 4.9 (10.35)	3.52 (1.95)	0.29 (-7.91, 8.48) 0.934 [0.03 (-1.15, 1.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9160
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.470.4.1: Total, Age group, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary							
Total							
Baseline	137	134 44.5 (8.19)		138	134 44.5 (7.83)		
Week 26		115 50.9 (7.60)			118 52.8 (7.38)		
Week 26 chg		113 6.8 (8.15)	6.63 (0.62)		114 8.4 (7.77)	8.47 (0.62)	1.84 (0.11, 3.56) 0.037 [0.23 (-0.03, 0.49)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4962
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.470.4.1: Total, Age group, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)											
Baseline	131	128	44.5 (8.33)			132	128	44.5 (7.88)			
Week 26		110	51.0 (7.69)				112	52.9 (7.45)			
Week 26 chg		108	6.8 (8.12)	6.67	(0.64)		108	8.5 (7.87)	8.63	(0.64)	1.97 (0.19, 3.75) 0.030 [0.25 (-0.02, 0.51)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4962
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.470.4.1: Total, Age group, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 44.2 (4.70)		6	6 45.3 (7.35)		
Week 26		5 49.2 (5.58)			6 50.5 (5.83)		
Week 26 chg		5 5.7 (9.71)	4.16 (2.54)		6 5.2 (5.02)	6.74 (2.18)	2.57 (-6.04, 11.18) 0.492 [0.34 (-0.85, 1.54)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4962
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.471.4.1: Total, Age group, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 16		121	49.5 (10.08)				117	50.1 (9.57)			
Week 16 chg		119	4.4 (8.65)	4.12	(0.70)		113	3.4 (8.59)	3.70	(0.72)	-0.42 (-2.41, 1.56) 0.675 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8429
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.471.4.1: Total, Age group, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	128 44.5 (11.31)		132	128 46.1 (9.66)		
Week 16		115 49.3 (10.06)			111 49.9 (9.62)		
Week 16 chg		113 4.6 (8.62)	4.32 (0.73)		107 3.5 (8.63)	3.76 (0.75)	-0.55 (-2.61, 1.50) 0.596 [-0.06 (-0.33, 0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8429
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.471.4.1: Total, Age group, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 52.8 (11.80)		6	6 50.0 (11.79)		
Week 16		6 52.6 (10.87)			6 53.1 (8.91)		
Week 16 chg		6 -0.2 (8.60)	-1.02 (2.60)		6 3.1 (8.60)	3.91 (2.60)	4.92 (-4.17, 14.02) 0.241 [0.57 (-0.58, 1.73)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8429
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.472.4.1: Total, Age group, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary											
Total											
Baseline	137	134	44.5 (8.19)			138	134	44.5 (7.83)			
Week 16		121	51.0 (7.75)				117	52.8 (6.79)			
Week 16 chg		119	6.8 (8.15)	6.60	(0.60)		113	8.0 (7.67)	8.20	(0.61)	1.60 (-0.09, 3.28) 0.063 [0.20 (-0.06, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1285
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.472.4.1: Total, Age group, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=18 and < 65)							
Baseline	131	128 44.5 (8.33)		132	128 44.5 (7.88)		
Week 16		115 51.2 (7.70)			111 53.0 (6.73)		
Week 16 chg		113 7.0 (8.21)	6.77 (0.61)		107 8.2 (7.79)	8.44 (0.63)	1.67 (-0.05, 3.39) 0.057 [0.21 (-0.06, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1285
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.472.4.1: Total, Age group, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Age (>=65)							
Baseline	6	6 44.2 (4.70)		6	6 45.3 (7.35)		
Week 16		6 47.8 (8.71)			6 49.0 (7.44)		
Week 16 chg		6 3.5 (6.72)	2.76 (2.24)		6 3.7 (2.96)	4.52 (2.24)	1.75 (-5.99, 9.50) 0.609 [0.34 (-0.80, 1.48)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1285
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.3.701.3.1: Total, Any TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	0.6677	0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504
Age (>=18 and < 65)		0.4032	1.06 (0.92, 1.22)	1.24 (0.75, 2.06)	4.1 (-5.6, 13.8)	80	(67.8)	175	171	(72.5)	478
Age (>=65)		0.5448	1.28 (0.59, 2.77)	1.80 (0.28, 11.4)	13.6 (-28, 55.6)	4	(50.0)	9	9	(56.3)	26

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 1.3.701.4.1: Total, Any TEAE, LP0162-1346, 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 + TCS n (%)	E	Tralokinumab Q2W + TCS n (%)	E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Age (>=18 and < 65)						131 62.5		132 62.4	
Age (>=65)						6 2.9		6 3.0	
Any system organ class									
Any preferred term									
Total	0.2387	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108 (78.8)	423	107 (77.5)	385
Age (>=18 and < 65)		0.9100	0.99 (0.87, 1.13)	0.97 (0.54, 1.72)	-0.6 (-11, 9.51)	102 (77.9)	411	102 (77.3)	375
Age (>=65)		0.4386	0.86 (0.63, 1.16)	0.00 (not est.)	-14 (-44, 15.6)	6 (100)	12	5 (83.3)	10

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 1.3.702.3.1: Total, Any drug-related TEAE, LP0162-1339, 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 + TCS n (%)	E	Tralokinumab Q2W + TCS n (%)	E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Age (>=18 and < 65)						118 35.6		236 70.1	
Age (>=65)						8 2.3		16 4.9	
Any system organ class									
Any preferred term									
Total	0.6414	0.0023	1.58 (1.16, 2.16)	2.11 (1.30, 3.42)	15.7 (6.11, 25.2)	34 (27.0)	61	108 (42.9)	232
Age (>=18 and < 65)		0.0021	1.60 (1.16, 2.20)	2.17 (1.32, 3.57)	16.4 (6.45, 26.3)	32 (27.1)	59	104 (44.1)	223
Age (>=65)		0.8760	1.17 (0.17, 7.81)	1.20 (0.15, 9.53)	3.4 (-34, 41.1)	2 (25.0)	2	4 (25.0)	9

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 1.3.702.4.1: Total, Any drug-related TEAE, LP0162-1346, 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 + TCS n (%)	E	Tralokinumab Q2W + TCS n (%)	E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Age (>=18 and < 65)						131 62.5		132 62.4	
Age (>=65)						6 2.9		6 3.0	
Any system organ class									
Any preferred term									
Total	0.3341	0.2852	1.19 (0.86, 1.65)	1.32 (0.80, 2.17)	6.1 (-5.0, 17.3)	43 (31.4)	94	52 (37.7)	105
Age (>=18 and < 65)		0.2084	1.25 (0.88, 1.75)	1.39 (0.83, 2.34)	7.3 (-4.0, 18.6)	39 (29.8)	90	49 (37.1)	102
Age (>=65)		0.4711	0.64 (0.18, 2.24)	0.38 (0.03, 4.94)	-24 (-81, 33.2)	4 (66.7)	4	3 (50.0)	3

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 1.3.703.3.1: Total, Any TEAE causing permanent discontinuation, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Age (>=18 and < 65)						118 35.6		236 70.1	
Age (>=65)						8 2.3		16 4.9	
Any system organ class									
Any preferred term									
Total	0.5086	0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1 (0.8)	1	6 (2.4)	8
Age (>=18 and < 65)		0.3875	2.47 (0.30, 20.7)	2.54 (0.29, 22.3)	1.3 (-1.2, 3.71)	1 (0.8)	1	5 (2.1)	5
Age (>=65)		0.5637			5.1 (-6.3, 16.5)	0 (0.0)	0	1 (6.3)	3

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 1.3.703.4.1: Total, Any TEAE causing permanent discontinuation, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Age (>=18 and < 65)						131	62.5		132	62.4	
Age (>=65)						6	2.9		6	3.0	
Any system organ class											
Any preferred term											
Total	Not est.	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3	(2.2)	4	1	(0.7)	1
Age (>=18 and < 65)		0.3127	0.33 (0.03, 3.21)	0.33 (0.03, 3.17)	-1.5 (-4.5, 1.44)	3	(2.3)	4	1	(0.8)	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. TEAE: Treatment emergent adverse events

Table 1.3.704.3.1: Total, Any mild TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	0.3414	0.1405	1.14 (0.95, 1.36)	1.41 (0.89, 2.23)	7.5 (-2.5, 17.5)	69	(54.8)	132	157	(62.3)	384
Age (>=18 and < 65)		0.2372	1.11 (0.93, 1.33)	1.33 (0.83, 2.13)	6.2 (-4.1, 16.6)	66	(55.9)	125	148	(62.7)	359
Age (>=65)		0.1820	1.85 (0.71, 4.82)	5.25 (0.47, 58.6)	28.8 (-6.0, 63.6)	3	(37.5)	7	9	(56.3)	25

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 1.3.704.4.1: Total, Any mild TEAE, LP0162-1346, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Analysis set							
N, Exposure(years)							
Total						137 65.4	138 65.4
Age (>=18 and < 65)						131 62.5	132 62.4
Age (>=65)						6 2.9	6 3.0
Any system organ class							
Any preferred term							
Total	0.5112	0.9615	1.00 (0.87, 1.16)	1.01 (0.60, 1.71)	0.3 (-10, 10.9)	98 (71.5) 293	99 (71.7) 300
Age (>=18 and < 65)		0.8602	1.01 (0.87, 1.18)	1.05 (0.61, 1.79)	1.0 (-9.9, 11.9)	93 (71.0) 285	95 (72.0) 291
Age (>=65)		0.8600	0.94 (0.49, 1.81)	0.75 (0.04, 15.0)	-4.8 (-54, 44.8)	5 (83.3) 8	4 (66.7) 9

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 1.3.705.3.1: Total, Any moderate TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	0.1965	0.6376	1.09 (0.75, 1.59)	1.13 (0.68, 1.85)	2.2 (-7.0, 11.4)	30	(23.8)	42	66	(26.2)	113
Age (>=18 and < 65)		0.4788	1.15 (0.78, 1.69)	1.20 (0.72, 2.01)	3.5 (-6.1, 13.0)	28	(23.7)	40	65	(27.5)	112
Age (>=65)		0.1730	0.24 (0.02, 2.27)	0.24 (0.02, 2.94)	-22 (-59, 14.7)	2	(25.0)	2	1	(6.3)	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. TEAE: Treatment emergent adverse events

Table 1.3.705.4.1: Total, Any moderate TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Age (>=18 and < 65)						131	62.5		132	62.4	
Age (>=65)						6	2.9		6	3.0	
Any system organ class											
Any preferred term											
Total	0.3336	0.0876	0.75 (0.53, 1.05)	0.65 (0.39, 1.07)	-9.8 (-21, 1.39)	53	(38.7)	121	40	(29.0)	82
Age (>=18 and < 65)		0.1401	0.77 (0.55, 1.09)	0.68 (0.41, 1.14)	-8.6 (-20, 2.78)	50	(38.2)	117	39	(29.5)	81
Age (>=65)		0.1755	0.25 (0.03, 2.02)	0.10 (0.00, 2.63)	-43 (-90, 4.73)	3	(50.0)	4	1	(16.7)	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. TEAE: Treatment emergent adverse events

Table 1.3.706.3.1: Total, Any severe TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	Not est.	0.1738	0.50 (0.18, 1.39)	0.48 (0.16, 1.41)	-2.8 (-7.3, 1.68)	7	(5.6)	10	7	(2.8)	7
Age (>=18 and < 65)		0.1653	0.49 (0.17, 1.37)	0.47 (0.16, 1.39)	-3.0 (-7.8, 1.73)	7	(5.9)	10	7	(3.0)	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 1.3.706.4.1: Total, Any severe TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Age (>=18 and < 65)						131	62.5		132	62.4	
Age (>=65)						6	2.9		6	3.0	
Any system organ class											
Any preferred term											
Total	Not est.	0.1235	0.37 (0.10, 1.38)	0.36 (0.09, 1.39)	-3.7 (-8.3, 0.97)	8 (5.8)		9	3 (2.2)		3
Age (>=18 and < 65)		0.1220	0.37 (0.10, 1.37)	0.36 (0.09, 1.38)	-3.8 (-8.7, 0.99)	8 (6.1)		9	3 (2.3)		3

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 1.3.707.3.1: Total, Death, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Age (>=18 and < 65)					118	35.6		236	70.1	
Age (>=65)					8	2.3		16	4.9	

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.

Table 1.3.707.4.1: Total, Death, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Age (>=18 and < 65)					131	62.5		132	62.4	
Age (>=65)					6	2.9		6	3.0	

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.

Table 1.3.708.3.1: Total, Any TE SAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	Not est.	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4	(3.2)	4	2	(0.8)	2
Age (>=18 and < 65)		0.0732	0.24 (0.04, 1.31)	0.23 (0.04, 1.31)	-2.6 (-6.1, 0.87)	4	(3.4)	4	2	(0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.3.708.4.1: Total, Any TE SAE, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Age (>=18 and < 65)						131 62.5		132 62.4	
Age (>=65)						6 2.9		6 3.0	
Any system organ class									
Any preferred term									
Total	Not est.	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5 (3.6)	9	1 (0.7)	1
Age (>=18 and < 65)		0.0981	0.20 (0.02, 1.67)	0.19 (0.02, 1.68)	-3.1 (-6.6, 0.54)	5 (3.8)	9	1 (0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.3.709.3.1: Total, Any drug-related TE SAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Age (>=18 and < 65)					118	35.6		236	70.1	
Age (>=65)					8	2.3		16	4.9	

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 1.3.709.4.1: Total, Any drug-related TE SAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Age (>=18 and < 65)						131	62.5		132	62.4	
Age (>=65)						6	2.9		6	3.0	
Any system organ class											
Any preferred term											
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)		3	0 (0.0)		0
Age (>=18 and < 65)		0.1557	0.00 (not est.)	0.00 (not est.)	-1.5 (-3.6, 0.57)	2 (1.5)		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 1.3.710.3.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Age (>=18 and < 65)					118	35.6		236	70.1	
Age (>=65)					8	2.3		16	4.9	

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 1.3.710.4.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Age (>=18 and < 65)						131 62.5		132 62.4	
Age (>=65)						6 2.9		6 3.0	
Any system organ class									
Any preferred term									
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)	3	0 (0.0)	0
Age (>=18 and < 65)		0.1557	0.00 (not est.)	0.00 (not est.)	-1.5 (-3.6, 0.57)	2 (1.5)	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 1.3.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	0.6677	0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504
Age (>=18 and < 65)		0.4032	1.06 (0.92, 1.22)	1.24 (0.75, 2.06)	4.1 (-5.6, 13.8)	80	(67.8)	175	171	(72.5)	478
Age (>=65)		0.5448	1.28 (0.59, 2.77)	1.80 (0.28, 11.4)	13.6 (-28, 55.6)	4	(50.0)	9	9	(56.3)	26
Eye disorders											
Any											
Total	0.3283	0.0191	3.12 (1.12, 8.68)	3.50 (1.17, 10.5)	6.7 (2.02, 11.5)	4	(3.2)	5	25	(9.9)	29
Age (>=18 and < 65)		0.0351	2.81 (1.01, 7.80)	3.14 (1.04, 9.49)	6.2 (1.30, 11.1)	4	(3.4)	5	23	(9.7)	27
Age (>=65)		0.3621			11.9 (-5.0, 28.7)	0	(0.0)	0	2	(12.5)	2
Gastrointestinal disorders											
Any											
Total	0.4277	0.2711	1.49 (0.73, 3.06)	1.55 (0.71, 3.40)	3.5 (-2.4, 9.43)	9	(7.1)	10	27	(10.7)	30
General disorders and administration site conditions											
Any											
Total	0.3027	0.0459	1.81 (0.99, 3.31)	1.99 (1.00, 3.94)	7.7 (0.80, 14.6)	12	(9.5)	13	43	(17.1)	66
Age (>=18 and < 65)		0.0697	1.72 (0.94, 3.14)	1.88 (0.94, 3.74)	7.3 (0.03, 14.6)	12	(10.2)	13	41	(17.4)	61
Age (>=65)		0.3621			11.9 (-5.0, 28.7)	0	(0.0)	0	2	(12.5)	5

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

11FEB21 10:07 LP0162-Payer /p_aetest/T_t_agr2_t11_39.txt

Table 1.3.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Injection site reaction											
Total	Not est.	0.0026			6.7 (3.63, 9.81)	0	(0.0)	0	17	(6.7)	30
Age (>=18 and < 65)		0.0041			6.4 (3.31, 9.58)	0	(0.0)	0	15	(6.4)	27
Age (>=65)		0.3621			11.9 (-5.0, 28.7)	0	(0.0)	0	2	(12.5)	3
Infections and infestations											
Any											
Total	0.0351	0.0346	1.30 (1.01, 1.69)	1.63 (1.03, 2.56)	11.1 (0.97, 21.2)	46	(36.5)	72	120	(47.6)	186
Age (>=18 and < 65)		0.0884	1.24 (0.96, 1.60)	1.49 (0.94, 2.37)	9.3 (-1.3, 19.8)	46	(39.0)	72	115	(48.7)	179
Age (>=65)		0.0678			37.3 (14.4, 60.1)	0	(0.0)	0	5	(31.3)	7
Upper respiratory tract infection											
Total	Not est.	0.3271	1.55 (0.64, 3.79)	1.60 (0.62, 4.11)	2.6 (-2.3, 7.57)	6	(4.8)	7	19	(7.5)	21
Conjunctivitis											
Total	0.5059	0.0087	3.46 (1.25, 9.58)	3.95 (1.33, 11.7)	7.8 (2.97, 12.7)	4	(3.2)	4	28	(11.1)	32
Age (>=18 and < 65)		0.0130	3.26 (1.18, 9.04)	3.69 (1.24, 10.9)	7.8 (2.63, 12.9)	4	(3.4)	4	27	(11.4)	31
Age (>=65)		0.1573			13.6 (-2.7, 29.8)	0	(0.0)	0	1	(6.3)	1
Viral upper respiratory tract infection											
Total	0.2333	0.0363	1.75 (1.02, 3.01)	2.00 (1.04, 3.85)	8.3 (1.16, 15.4)	14	(11.1)	18	49	(19.4)	64
Age (>=18 and < 65)		0.0604	1.65 (0.96, 2.84)	1.88 (0.97, 3.63)	7.8 (0.25, 15.3)	14	(11.9)	18	47	(19.9)	62
Age (>=65)		0.3621			11.9 (-5.0, 28.7)	0	(0.0)	0	2	(12.5)	2
Injury, poisoning and procedural complications											
Any											
Total	0.3626	0.5974	1.31 (0.48, 3.60)	1.32 (0.46, 3.77)	1.2 (-3.2, 5.63)	5	(4.0)	6	13	(5.2)	14
Musculoskeletal and connective tissue disorders											
Any											

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

11FEB21 10:07 LP0162-Payer /p_aetest/T_t_agr2_t11_39.txt

Table 1.3.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total	0.4078	0.2269	1.79 (0.68, 4.68)	1.86 (0.67, 5.14)	3.2 (-1.5, 7.81)	5	(4.0)	6	18	(7.1)	20
Nervous system disorders											
Any											
Total	Not est.	0.1130	1.80 (0.85, 3.78)	1.93 (0.85, 4.40)	5.1 (-.65, 10.8)	8	(6.3)	11	29	(11.5)	37
Headache											
Total	Not est.	0.1663	1.81 (0.77, 4.29)	1.93 (0.75, 4.95)	3.9 (-1.1, 8.91)	6	(4.8)	9	22	(8.7)	26
Respiratory, thoracic and mediastinal disorders											
Any											
Total	0.1858	0.5541	1.21 (0.64, 2.28)	1.24 (0.61, 2.50)	2.0 (-4.5, 8.52)	12	(9.5)	14	29	(11.5)	39
Skin and subcutaneous tissue disorders											
Any											
Total	0.8351	0.0628	0.63 (0.38, 1.02)	0.58 (0.32, 1.03)	-7.1 (-15, 0.81)	24	(19.0)	28	30	(11.9)	36
Dermatitis atopic											
Total	0.3494	0.0125	0.30 (0.11, 0.82)	0.28 (0.10, 0.80)	-5.5 (-11, -.44)	10	(7.9)	12	6	(2.4)	8
Age (>=18 and < 65)		0.0253	0.33 (0.12, 0.91)	0.31 (0.11, 0.90)	-5.1 (-10, 0.10)	9	(7.6)	11	6	(2.5)	8
Age (>=65)		0.1573	0.00 (not est.)	0.00 (not est.)	-14 (-38, 11.0)	1	(12.5)	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. TEAE: Treatment emergent adverse events

Table 1.3.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Age (>=18 and < 65)						131	62.5		132	62.4	
Age (>=65)						6	2.9		6	3.0	
Any system organ class											
Any preferred term											
Total	0.2387	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385
Age (>=18 and < 65)		0.9100	0.99 (0.87, 1.13)	0.97 (0.54, 1.72)	-0.6 (-11, 9.51)	102	(77.9)	411	102	(77.3)	375
Age (>=65)		0.4386	0.86 (0.63, 1.16)	0.00 (not est.)	-14 (-44, 15.6)	6	(100)	12	5	(83.3)	10
Eye disorders											
Any											
Total	0.1524	0.2842	1.54 (0.69, 3.44)	1.61 (0.67, 3.84)	3.6 (-3.0, 10.1)	9	(6.6)	14	14	(10.1)	17
Gastrointestinal disorders											
Any											
Total	Not est.	0.8349	0.93 (0.48, 1.81)	0.92 (0.44, 1.95)	-0.8 (-8.3, 6.68)	16	(11.7)	23	15	(10.9)	18
General disorders and administration site conditions											
Any											
Total	0.3483	0.1576	1.59 (0.83, 3.03)	1.70 (0.81, 3.57)	5.6 (-2.1, 13.3)	13	(9.5)	16	21	(15.2)	27
Infections and infestations											
Any											
Total	0.7850	0.2533	0.89 (0.72, 1.09)	0.76 (0.47, 1.22)	-6.8 (-18, 4.82)	83	(60.6)	152	74	(53.6)	144

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

11FEB21 09:47 LP0162-Payer /p_aetest/T_t_agr2_t11_46.txt

Table 1.3.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Upper respiratory tract infection											
Total	Not est.	0.9930	1.00 (0.43, 2.31)	1.00 (0.40, 2.47)	-0.0 (-6.2, 6.12)	10	(7.3)	11	10	(7.2)	12
Viral upper respiratory tract infection											
Total	0.5170	0.7928	1.05 (0.71, 1.57)	1.08 (0.63, 1.84)	1.4 (-9.0, 11.8)	35	(25.5)	46	37	(26.8)	53
Injury, poisoning and procedural complications											
Any											
Total	0.8715	0.5243	1.29 (0.59, 2.84)	1.32 (0.56, 3.08)	2.1 (-4.5, 8.74)	10	(7.3)	12	13	(9.4)	16
Musculoskeletal and connective tissue disorders											
Any											
Total	0.1793	0.4116	1.27 (0.72, 2.24)	1.32 (0.68, 2.57)	3.5 (-4.9, 12.0)	18	(13.1)	28	23	(16.7)	25
Nervous system disorders											
Any											
Total	Not est.	0.6516	1.13 (0.66, 1.94)	1.16 (0.61, 2.20)	2.0 (-6.7, 10.8)	21	(15.3)	31	24	(17.4)	33
Headache											
Total	Not est.	0.1506	1.61 (0.84, 3.09)	1.71 (0.82, 3.57)	5.7 (-2.0, 13.5)	13	(9.5)	18	21	(15.2)	25
Respiratory, thoracic and mediastinal disorders											
Any											
Total	Not est.	0.0335	0.55 (0.31, 0.96)	0.49 (0.25, 0.95)	-9.5 (-18, -.84)	29	(21.2)	38	16	(11.6)	21
Age (>=18 and < 65)		0.0317	0.55 (0.31, 0.96)	0.48 (0.25, 0.94)	-10 (-19, -.98)	29	(22.1)	38	16	(12.1)	21
Skin and subcutaneous tissue disorders											
Any											
Total	0.1142	0.1365	0.71 (0.46, 1.12)	0.65 (0.37, 1.15)	-7.5 (-17, 2.33)	36	(26.3)	59	26	(18.8)	44

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

11FEB21 09:47 LP0162-Payer /p_aetest/T_t_agr2_t11_46.txt

Table 1.3.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Dermatitis atopic									
Total	Not est.	0.0498	0.44 (0.19, 1.03)	0.41 (0.16, 1.02)	-6.6 (-13, -.07)	16 (11.7)	26	7 (5.1)	11
Age (>=18 and < 65)		0.0483	0.43 (0.18, 1.02)	0.40 (0.16, 1.01)	-6.9 (-14, -.12)	16 (12.2)	26	7 (5.3)	11
Vascular disorders									
Any									
Total	0.5027	0.0596	0.36 (0.12, 1.10)	0.34 (0.10, 1.09)	-5.2 (-11, 0.16)	11 (8.0)	12	4 (2.9)	6

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 1.3.712.3.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Age (>=18 and < 65)						118 35.6		236 70.1	
Age (>=65)						8 2.3		16 4.9	
Any system organ class									
Any preferred term									
Total	Not est.	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4 (3.2)	4	2 (0.8)	2
Age (>=18 and < 65)		0.0732	0.24 (0.04, 1.31)	0.23 (0.04, 1.31)	-2.6 (-6.1, 0.87)	4 (3.4)	4	2 (0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.3.712.4.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Age (>=18 and < 65)						131 62.5		132 62.4	
Age (>=65)						6 2.9		6 3.0	
Any system organ class									
Any preferred term									
Total	Not est.	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5 (3.6)	9	1 (0.7)	1
Age (>=18 and < 65)		0.0981	0.20 (0.02, 1.67)	0.19 (0.02, 1.68)	-3.1 (-6.6, 0.54)	5 (3.8)	9	1 (0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.3.713.3.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	0.5086	0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1	(0.8)	1	6	(2.4)	8
Age (>=18 and < 65)		0.3875	2.47 (0.30, 20.7)	2.54 (0.29, 22.3)	1.3 (-1.2, 3.71)	1	(0.8)	1	5	(2.1)	5
Age (>=65)		0.5637			5.1 (-6.3, 16.5)	0	(0.0)	0	1	(6.3)	3
General disorders and administration site conditions											
Any											
Total	Not est.	0.3123			0.8 (-.30, 1.91)	0	(0.0)	0	2	(0.8)	2
Hernia											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	1
Injection site reaction											
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0	(0.0)	0	1	(0.4)	1
Infections and infestations											
Any											
Total	Not est.	0.2229			1.2 (-.15, 2.52)	0	(0.0)	0	3	(1.2)	3
Conjunctivitis											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	1
Otitis media											
Total	Not est.	0.4954			0.4 (-.38, 1.14)	0	(0.0)	0	1	(0.4)	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. TE SAE: Treatment emergent serious adverse events

Table 1.3.713.3.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Influenza									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Musculoskeletal and connective tissue disorders									
Any									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Myalgia									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Psychiatric disorders									
Any									
Total	Not est.	0.3123			0.8 (-.30, 1.91)	0 (0.0)	0	2 (0.8)	2
Anxiety									
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0 (0.0)	0	1 (0.4)	1
Mood altered									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Dermatitis atopic									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.3.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Age (>=18 and < 65)						131 62.5		132 62.4	
Age (>=65)						6 2.9		6 3.0	
Any system organ class									
Any preferred term									
Total	Not est.	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3 (2.2)	4	1 (0.7)	1
Age (>=18 and < 65)		0.3127	0.33 (0.03, 3.21)	0.33 (0.03, 3.17)	-1.5 (-4.5, 1.44)	3 (2.3)	4	1 (0.8)	1
General disorders and administration site conditions									
Any									
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0 (0.0)	0	1 (0.7)	1
Injection site pain									
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0 (0.0)	0	1 (0.7)	1
Nervous system disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Cerebrovascular accident									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Psychiatric disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	2	0 (0.0)	0
Depressed mood									

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

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Table 1.3.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Suicidal ideation									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis atopic									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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. TE SAE: Treatment emergent serious adverse events

Table 1.3.714.3.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	0.4398	0.0185	2.40 (1.10, 5.22)	2.71 (1.15, 6.37)	7.8 (2.10, 13.5)	7	(5.6)	7	34	(13.5)	39
Age (>=18 and < 65)		0.0271	2.29 (1.05, 4.98)	2.57 (1.09, 6.05)	7.7 (1.66, 13.7)	7	(5.9)	7	33	(14.0)	38
Age (>=65)		0.1573			13.6 (-2.7, 29.8)	0	(0.0)	0	1	(6.3)	1
Eye disorders											
Any											
Total	Not est.	0.6213	1.48 (0.31, 7.12)	1.50 (0.30, 7.61)	0.8 (-2.1, 3.64)	2	(1.6)	2	6	(2.4)	7
Keratitis											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	1
Conjunctivitis allergic											
Total	Not est.	0.8018	1.23 (0.25, 6.16)	1.24 (0.23, 6.53)	0.4 (-2.4, 3.13)	2	(1.6)	2	5	(2.0)	6
Infections and infestations											
Any											
Total	0.4798	0.0205	2.77 (1.10, 7.00)	3.04 (1.14, 8.11)	7.0 (1.91, 12.1)	5	(4.0)	5	28	(11.1)	32
Age (>=18 and < 65)		0.0294	2.63 (1.04, 6.66)	2.87 (1.07, 7.66)	6.9 (1.53, 12.3)	5	(4.2)	5	27	(11.4)	31
Age (>=65)		0.1573			13.6 (-2.7, 29.8)	0	(0.0)	0	1	(6.3)	1
Conjunctivitis viral											
Total	Not est.	0.1605	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1	(0.8)	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

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Table 1.3.714.3.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Conjunctivitis											
Total	0.5059	0.0087	3.46 (1.25, 9.58)	3.95 (1.33, 11.7)	7.8 (2.97, 12.7)	4	(3.2)	4	28	(11.1)	32
Age (>=18 and < 65)		0.0130	3.26 (1.18, 9.04)	3.69 (1.24, 10.9)	7.8 (2.63, 12.9)	4	(3.4)	4	27	(11.4)	31
Age (>=65)		0.1573			13.6 (-2.7, 29.8)	0	(0.0)	0	1	(6.3)	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 1.3.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Age (>=18 and < 65)						131	62.5		132	62.4	
Age (>=65)						6	2.9		6	3.0	
Any system organ class											
Any preferred term											
Total	0.0030	0.0780	2.14 (0.90, 5.07)	2.28 (0.90, 5.77)	5.8 (-.58, 12.2)	7	(5.1)	9	15	(10.9)	17
Age (>=18 and < 65)		0.0095	3.72 (1.27, 10.9)	4.07 (1.31, 12.6)	8.3 (2.15, 14.5)	4	(3.1)	6	15	(11.4)	17
Age (>=65)		0.1060	0.00 (not est.)	0.00 (not est.)	-43 (-88, 2.04)	3	(50.0)	3	0	(0.0)	0
Eye disorders											
Any											
Total	0.1068	0.1593	2.23 (0.71, 7.03)	2.30 (0.70, 7.57)	3.6 (-1.4, 8.64)	4	(2.9)	4	9	(6.5)	11
Lacrimation increased											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Exposure keratitis											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Atopic keratoconjunctivitis											
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0	(0.0)	0	1	(0.7)	1
Conjunctivitis allergic											
Total	0.1472	0.5286	1.48 (0.43, 5.11)	1.50 (0.42, 5.40)	1.4 (-3.0, 5.88)	4	(2.9)	4	6	(4.3)	8
Infections and infestations											
Any											
Total	0.0278	0.5286	1.49 (0.43, 5.24)	1.51 (0.42, 5.49)	1.4 (-3.0, 5.84)	4	(2.9)	5	6	(4.3)	6

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

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Table 1.3.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Conjunctivitis									
Total	Not est.	0.1591	2.96 (0.61, 14.5)	3.05 (0.60, 15.4)	2.9 (-1.1, 6.81)	2 (1.5)	3	6 (4.3)	6
Keratitis viral									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Herpes ophthalmic									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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 1.3.715.3.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Age (>=18 and < 65)					118	35.6		236	70.1	
Age (>=65)					8	2.3		16	4.9	

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 1.3.715.4.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS N	Placebo + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total						137	65.4			138	65.4	
Age (>=18 and < 65)						131	62.5			132	62.4	
Age (>=65)						6	2.9			6	3.0	

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 1.3.716.3.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Age (>=18 and < 65)						118 35.6		236 70.1	
Age (>=65)						8 2.3		16 4.9	
Any system organ class									
Any preferred term									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	1
Age (>=18 and < 65)		0.5938	0.48 (0.03, 7.41)	0.48 (0.03, 7.57)	-0.4 (-2.3, 1.42)	1 (0.8)	1	1 (0.4)	1
Infections and infestations									
Any									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	1
Eczema herpeticum									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	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 1.3.716.4.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Age (>=18 and < 65)						131	62.5		132	62.4	
Age (>=65)						6	2.9		6	3.0	
Any system organ class											
Any preferred term											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	2
Age (>=18 and < 65)		0.3173			0.8 (-.72, 2.24)	0	(0.0)	0	1	(0.8)	2
Infections and infestations											
Any											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	2
Eczema herpeticum											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	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 1.3.717.3.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Age (>=18 and < 65)					118	35.6		236	70.1	
Age (>=65)					8	2.3		16	4.9	

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 1.3.717.4.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Age (>=18 and < 65)					131	62.5		132	62.4	
Age (>=65)					6	2.9		6	3.0	

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 1.3.718.3.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Age (>=18 and < 65)					118	35.6		236	70.1	
Age (>=65)					8	2.3		16	4.9	

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 1.3.718.4.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Age (>=18 and < 65)					131	62.5		132	62.4	
Age (>=65)					6	2.9		6	3.0	

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 1.3.719.3.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Age (>=18 and < 65)					118	35.6		236	70.1	
Age (>=65)					8	2.3		16	4.9	

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 1.3.719.4.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Age (>=18 and < 65)					131	62.5		132	62.4	
Age (>=65)					6	2.9		6	3.0	

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 1.3.720.3.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Age (>=18 and < 65)						118 35.6		236 70.1	
Age (>=65)						8 2.3		16 4.9	
Any system organ class									
Any preferred term									
Total	0.1418	0.0327	0.29 (0.09, 0.97)	0.27 (0.08, 0.96)	-3.9 (-8.2, 0.34)	7 (5.6)	9	4 (1.6)	4
Age (>=18 and < 65)		0.0143	0.22 (0.06, 0.83)	0.21 (0.05, 0.82)	-4.6 (-9.1, -.12)	7 (5.9)	9	3 (1.3)	3
Age (>=65)		0.4795			6.8 (-6.2, 19.8)	0 (0.0)	0	1 (6.3)	1
Infections and infestations									
Any									
Total	0.1418	0.0327	0.29 (0.09, 0.97)	0.27 (0.08, 0.96)	-3.9 (-8.2, 0.34)	7 (5.6)	9	4 (1.6)	4
Age (>=18 and < 65)		0.0143	0.22 (0.06, 0.83)	0.21 (0.05, 0.82)	-4.6 (-9.1, -.12)	7 (5.9)	9	3 (1.3)	3
Age (>=65)		0.4795			6.8 (-6.2, 19.8)	0 (0.0)	0	1 (6.3)	1
Infected dermal cyst									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Paronychia									
Total	Not est.	0.1675	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Impetigo									
Total	Not est.	0.6369	0.52 (0.03, 8.40)	0.52 (0.03, 8.30)	-0.4 (-2.1, 1.35)	1 (0.8)	1	1 (0.4)	1
Dermatitis infected									
Total	Not est.	0.0048	0.00 (not est.)	0.00 (not est.)	-3.2 (-6.2, -.11)	4 (3.2)	6	0 (0.0)	0
Age (>=18 and < 65)		0.0049	0.00 (not est.)	0.00 (not est.)	-3.4 (-6.6, -.12)	4 (3.4)	6	0 (0.0)	0
Cellulitis									

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 1.3.720.3.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for inter-action	CMH				Placebo + TCS		Tralokinumab Q2W + TCS	
		p-value	RR 95%CI	OR 95%CI	RD 95%CI	n (%)	E	n (%)	E
Total	0.3265	0.9983	1.00 (0.09, 11.2)	1.00 (0.09, 11.1)	-0.0 (-1.9, 1.90)	1 (0.8)	1	2 (0.8)	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 1.3.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Age (>=18 and < 65)						131 62.5		132 62.4	
Age (>=65)						6 2.9		6 3.0	
Any system organ class									
Any preferred term									
Total	Not est.	0.0178	0.12 (0.02, 0.99)	0.12 (0.01, 0.96)	-5.1 (-9.3, -.93)	8 (5.8)	12	1 (0.7)	1
Age (>=18 and < 65)		0.0175	0.12 (0.02, 0.98)	0.12 (0.01, 0.96)	-5.3 (-9.7, -.98)	8 (6.1)	12	1 (0.8)	1
Infections and infestations									
Any									
Total	Not est.	0.0311	0.14 (0.02, 1.15)	0.13 (0.02, 1.12)	-4.4 (-8.3, -.44)	7 (5.1)	11	1 (0.7)	1
Age (>=18 and < 65)		0.0310	0.14 (0.02, 1.14)	0.14 (0.02, 1.12)	-4.6 (-8.7, -.46)	7 (5.3)	11	1 (0.8)	1
Staphylococcal skin infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Cellulitis									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Wound infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Oral herpes									
Total	Not est.	0.3067	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.2, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis infected									
Total	Not est.	0.1718	0.24 (0.03, 2.19)	0.24 (0.03, 2.19)	-2.2 (-5.4, 0.94)	4 (2.9)	7	1 (0.7)	1

Skin and subcutaneous tissue disorders
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 1.3.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Hand dermatitis									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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 1.3.721.3.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Age (>=18 and < 65)						118 35.6		236 70.1	
Age (>=65)						8 2.3		16 4.9	
Any system organ class									
Any preferred term									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Age (>=18 and < 65)		0.1545	0.00 (not est.)	0.00 (not est.)	-0.9 (-2.5, 0.81)	1 (0.8)	1	0 (0.0)	0
Infections and infestations									
Any									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Dermatitis infected									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	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. TESAESI: Treatment emergent serious adverse events of special interest

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Table 1.3.721.4.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Age (>=18 and < 65)					131	62.5		132	62.4	
Age (>=65)					6	2.9		6	3.0	

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

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Table 1.3.722.3.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	0.3322	0.1972	1.10 (0.95, 1.27)	1.37 (0.85, 2.22)	6.2 (-3.3, 15.8)	81	(64.3)	168	178	(70.6)	494
Age (>=18 and < 65)		0.3203	1.07 (0.93, 1.24)	1.29 (0.78, 2.12)	4.9 (-4.9, 14.8)	78	(66.1)	162	169	(71.6)	468
Age (>=65)		0.2504	1.76 (0.64, 4.86)	3.00 (0.47, 19.3)	27.1 (-15, 69.0)	3	(37.5)	6	9	(56.3)	26

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 1.3.722.4.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Age (>=18 and < 65)						131	62.5		132	62.4	
Age (>=65)						6	2.9		6	3.0	
Any system organ class											
Any preferred term											
Total	0.2384	0.8030	0.98 (0.87, 1.12)	0.93 (0.53, 1.64)	-1.3 (-11, 8.62)	107	(78.1)	391	106	(76.8)	361
Age (>=18 and < 65)		0.9119	0.99 (0.87, 1.13)	0.97 (0.55, 1.72)	-0.6 (-11, 9.63)	101	(77.1)	379	101	(76.5)	351
Age (>=65)		0.4386	0.86 (0.63, 1.16)	0.00 (not est.)	-14 (-44, 15.6)	6	(100)	12	5	(83.3)	10

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 1.3.723.3.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Age (>=18 and < 65)						118	35.6		236	70.1	
Age (>=65)						8	2.3		16	4.9	
Any system organ class											
Any preferred term											
Total	Not est.	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4	(3.2)	4	2	(0.8)	2
Age (>=18 and < 65)		0.0732	0.24 (0.04, 1.31)	0.23 (0.04, 1.31)	-2.6 (-6.1, 0.87)	4	(3.4)	4	2	(0.8)	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. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.3.723.4.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Age (>=18 and < 65)						131 62.5		132 62.4	
Age (>=65)						6 2.9		6 3.0	
Any system organ class									
Any preferred term									
Total	Not est.	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5 (3.6)	8	1 (0.7)	1
Age (>=18 and < 65)		0.0981	0.20 (0.02, 1.67)	0.19 (0.02, 1.68)	-3.1 (-6.6, 0.54)	5 (3.8)	8	1 (0.8)	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. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.4.101.3.1.1: Total, Male, Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	83	125
Age (years)		
Mean (sd)	36.3 (14.5)	40.7 (15.3)
Gender		
Male	83 (100%)	125 (100%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	26.4 (4.2)	27.1 (6.0)
Race		
Asian	20 (24.1%)	10 (8.0%)
Black	6 (7.2%)	4 (3.2%)
White	54 (65.1%)	104 (83.2%)
Other	3 (3.6%)	7 (5.6%)
Geographic region		
Europe	54 (65.1%)	76 (60.8%)
USA	29 (34.9%)	49 (39.2%)
Body surface area (BSA) with AD (%)		
Mean (sd)	54.3 (26.2)	52.2 (24.2)
Duration of AD (years)		
Mean (sd)	27.9 (14.7)	29.8 (17.3)
Eczema Area and Severity Index (EASI)		
Mean (sd)	32.3 (13.6)	30.6 (12.8)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	36 (43.4%)	64 (51.2%)
Severe [IGA=4]	47 (56.6%)	61 (48.8%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.7 (1.5)	7.6 (1.6)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.9 (2.4)	6.9 (2.2)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	69.5 (14.1)	68.2 (13.6)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	17.0 (7.2)	17.1 (7.3)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	12.2 (7.7)	11.5 (7.3)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	58.4 (23.1)	58.0 (23.9)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.613 (0.28)	0.553 (0.29)
Patients that have tried systemic corticosteroids (%)		
No	26 (31.3%)	50 (40.0%)
Yes	57 (68.7%)	75 (60.0%)
Previous number of treatments with systemic immunosuppressants*		
0	37 (44.6%)	79 (63.2%)
1	28 (33.7%)	28 (22.4%)
2	14 (16.9%)	11 (8.8%)
3	3 (3.6%)	4 (3.2%)
4		3 (2.4%)
5	1 (1.2%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.4.101.3.2.1: Total, Female, Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	43	127
Age (years)		
Mean (sd)	40.6 (15.2)	38.8 (15.4)
Gender		
Female	43 (100%)	127 (100%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	28.2 (7.4)	28.1 (7.2)
Race		
Asian	4 (9.3%)	7 (5.5%)
Black	6 (14.0%)	18 (14.2%)
White	30 (69.8%)	99 (78.0%)
Other	3 (7.0%)	3 (2.4%)
Geographic region		
Europe	18 (41.9%)	71 (55.9%)
USA	25 (58.1%)	56 (44.1%)
Body surface area (BSA) with AD (%)		
Mean (sd)	38.4 (22.2)	42.9 (21.5)
Duration of AD (years)		
Mean (sd)	30.3 (15.9)	26.1 (15.3)
Eczema Area and Severity Index (EASI)		
Mean (sd)	26.8 (10.2)	27.0 (10.8)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	30 (69.8%)	72 (56.7%)
Severe [IGA=4]	13 (30.2%)	55 (43.3%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	8.1 (1.4)	7.7 (1.5)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.4 (1.8)	6.9 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	67.7 (11.3)	65.7 (12.8)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	17.7 (7.2)	18.1 (6.9)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	11.1 (7.7)	11.9 (7.4)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	61.4 (23.2)	60.2 (26.1)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.543 (0.28)	0.570 (0.28)
Patients that have tried systemic corticosteroids (%)		
No	15 (34.9%)	55 (43.3%)
Yes	28 (65.1%)	72 (56.7%)
Previous number of treatments with systemic immunosuppressants*		
0	25 (58.1%)	80 (63.0%)
1	11 (25.6%)	36 (28.3%)
2	4 (9.3%)	8 (6.3%)
3	2 (4.7%)	1 (0.8%)
4	1 (2.3%)	1 (0.8%)
5		1 (0.8%)

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.4.101.4.1.1: Total, Male, Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	83	81
Age (years)		
Mean (sd)	36.9 (13.8)	38.4 (14.6)
Gender		
Male	83 (100%)	81 (100%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	25.7 (5.0)	25.4 (3.6)
Race		
White	83 (100%)	79 (97.5%)
Other		2 (2.5%)
Geographic region		
Europe	83 (100%)	81 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	55.7 (23.3)	53.8 (21.3)
Duration of AD (years)		
Mean (sd)	24.0 (13.7)	27.3 (14.6)
Eczema Area and Severity Index (EASI)		
Mean (sd)	34.3 (12.7)	31.3 (10.9)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	46 (55.4%)	41 (50.6%)
Severe [IGA=4]	37 (44.6%)	40 (49.4%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.3 (1.3)	7.0 (1.4)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.9 (1.5)	6.1 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	70.0 (12.1)	69.5 (12.2)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	15.8 (6.1)	15.0 (6.2)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	10.4 (6.6)	10.3 (6.0)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	55.1 (21.7)	56.4 (19.0)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.605 (0.22)	0.636 (0.23)
Patients that have tried systemic corticosteroids (%)		
No	25 (30.1%)	26 (32.1%)
Yes	58 (69.9%)	55 (67.9%)
Previous number of treatments with systemic immunosuppressants*		
0	13 (15.7%)	13 (16.0%)
1	44 (53.0%)	49 (60.5%)
2	19 (22.9%)	13 (16.0%)
3	6 (7.2%)	6 (7.4%)
4	1 (1.2%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.4.101.4.2.1: Total, Female, Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	54	57
Age (years)		
Mean (sd)	34.9 (13.6)	34.6 (14.5)
Gender		
Female	54 (100%)	57 (100%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	26.0 (6.8)	24.8 (5.0)
Race		
Asian	1 (1.9%)	
Black	1 (1.9%)	
White	52 (96.3%)	56 (98.2%)
Other		1 (1.8%)
Geographic region		
Europe	54 (100%)	57 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	54.4 (22.4)	54.5 (22.7)
Duration of AD (years)		
Mean (sd)	27.5 (14.6)	26.7 (12.8)
Eczema Area and Severity Index (EASI)		
Mean (sd)	33.2 (14.7)	33.2 (12.3)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	24 (44.4%)	27 (47.4%)
Severe [IGA=4]	30 (55.6%)	30 (52.6%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.7 (1.4)	7.6 (1.4)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.9 (1.8)	6.7 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	72.0 (13.9)	71.2 (11.9)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	17.2 (6.6)	17.1 (6.8)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	13.9 (8.3)	11.3 (6.9)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	48.5 (21.9)	56.9 (21.3)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.570 (0.26)	0.632 (0.22)
Patients that have tried systemic corticosteroids (%)		
No	21 (38.9%)	15 (26.3%)
Yes	33 (61.1%)	42 (73.7%)
Previous number of treatments with systemic immunosuppressants*		
0	10 (18.5%)	9 (15.8%)
1	34 (63.0%)	36 (63.2%)
2	8 (14.8%)	9 (15.8%)
3		2 (3.5%)
4	1 (1.9%)	1 (1.8%)
5	1 (1.9%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.4.102.3.1: Total, Male, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Male				
Analysis set				
N	83		125	
Blood and lymphatic system disorders				
Lymphadenopathy	1	(1.2)		
Dermatopathic lymphadenopathy			1	(0.8)
Eosinophilia			1	(0.8)
Hypereosinophilic syndrome			1	(0.8)
Lymphadenitis			1	(0.8)
Cardiac disorders				
Atrial fibrillation			2	(1.6)
Bundle branch block right			2	(1.6)
Cardiac failure chronic			2	(1.6)
Atrioventricular block first degree	1	(1.2)		
Ventricular extrasystoles	1	(1.2)		
Angina pectoris			1	(0.8)
Arrhythmia			1	(0.8)
Bradycardia			1	(0.8)
Myocardial infarction			1	(0.8)
Congenital, familial and genetic disorders				
Atrial septal defect	2	(2.4)		
Gilbert's syndrome	2	(2.4)		
Ichthyosis	1	(1.2)	1	(0.8)
Multiple lentigines syndrome	1	(1.2)		
Deafness congenital			1	(0.8)
Sickle cell trait			1	(0.8)
Tourette's disorder			1	(0.8)
Type V hyperlipidaemia			1	(0.8)
Ear and labyrinth disorders				
Deafness bilateral	1	(1.2)	2	(1.6)
Deafness			1	(0.8)
Tinnitus			1	(0.8)
Vertigo			1	(0.8)
Endocrine disorders				
Hypothyroidism	2	(2.4)	3	(2.4)
Eye disorders				
Conjunctivitis allergic	16	(19.3)	27	(21.6)
Atopic keratoconjunctivitis	1	(1.2)	4	(3.2)
Cataract	1	(1.2)	3	(2.4)
Dry eye			2	(1.6)
Blepharitis	1	(1.2)		
Keratitis	1	(1.2)		
Keratoconus	1	(1.2)	1	(0.8)
Allergic keratitis			1	(0.8)
Blindness			1	(0.8)
Blindness day			1	(0.8)
Blindness unilateral			1	(0.8)
Ectropion			1	(0.8)
Eye pruritus			1	(0.8)
Glaucoma			1	(0.8)
Myopia			1	(0.8)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	1	(1.2)	11	(8.8)
Dyspepsia			3	(2.4)
Haemorrhoids			3	(2.4)
Irritable bowel syndrome			2	(1.6)
Cheilitis	1	(1.2)		
Chronic gastritis	1	(1.2)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.102.3.1: Total, Male, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Male		
Gastrointestinal disorders		
Abdominal distension		1 (0.8)
Colitis ulcerative		1 (0.8)
Constipation		1 (0.8)
Oesophagitis		1 (0.8)
General disorders and administration site conditions		
Drug intolerance		2 (1.6)
Asthenia		1 (0.8)
Drug chemical incompatibility		1 (0.8)
Gait disturbance		1 (0.8)
Hernia		1 (0.8)
Pain		1 (0.8)
Peripheral swelling		1 (0.8)
Hepatobiliary disorders		
Hyperbilirubinaemia	1 (1.2)	
Cholelithiasis		1 (0.8)
Immune system disorders		
Seasonal allergy	42 (50.6)	59 (47.2)
Food allergy	32 (38.6)	41 (32.8)
Hypersensitivity	7 (8.4)	8 (6.4)
Allergy to animal	6 (7.2)	9 (7.2)
Multiple allergies	2 (2.4)	8 (6.4)
Drug hypersensitivity	5 (6.0)	7 (5.6)
Mite allergy	4 (4.8)	2 (1.6)
Dust allergy		6 (4.8)
Allergy to plants		2 (1.6)
Milk allergy	1 (1.2)	2 (1.6)
Rubber sensitivity	1 (1.2)	2 (1.6)
Allergy to metals	1 (1.2)	1 (0.8)
Reaction to colouring		1 (0.8)
Infections and infestations		
Herpes simplex	4 (4.8)	3 (2.4)
Oral herpes	2 (2.4)	2 (1.6)
Rhinitis	2 (2.4)	2 (1.6)
Conjunctivitis	1 (1.2)	1 (0.8)
Eczema herpeticum		1 (0.8)
Folliculitis		1 (0.8)
Sinusitis		1 (0.8)
Tinea versicolour		1 (0.8)
Injury, poisoning and procedural complications		
Ligament rupture	1 (1.2)	
Foot fracture		1 (0.8)
Joint injury		1 (0.8)
Meniscus injury		1 (0.8)
Tendon injury		1 (0.8)
Tendon rupture		1 (0.8)
Ulnar nerve injury		1 (0.8)
Investigations		
Blood cholesterol increased	2 (2.4)	2 (1.6)
Alanine aminotransferase increased	1 (1.2)	1 (0.8)
Basophil count decreased	1 (1.2)	
Blood bilirubin increased	1 (1.2)	
Blood immunoglobulin E increased	1 (1.2)	1 (0.8)
Blood lactate dehydrogenase increased	1 (1.2)	
Blood pressure increased	1 (1.2)	
Blood triglycerides increased	1 (1.2)	
Cardiac murmur	1 (1.2)	
Electrocardiogram QT shortened	1 (1.2)	

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.102.3.1: Total, Male, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Male				
Investigations				
Gamma-glutamyltransferase increased	1	(1.2)		
Low density lipoprotein increased	1	(1.2)		
Mean cell volume decreased	1	(1.2)		
Eosinophil count increased			1	(0.8)
Metabolism and nutrition disorders				
Obesity			6	(4.8)
Lactose intolerance			5	(4.0)
Type 2 diabetes mellitus	2	(2.4)	5	(4.0)
Gout	3	(3.6)	3	(2.4)
Vitamin D deficiency	2	(2.4)	1	(0.8)
Gluten sensitivity			3	(2.4)
Hyperlipidaemia			3	(2.4)
Hypertriglyceridaemia			3	(2.4)
Diabetes mellitus	1	(1.2)	2	(1.6)
Hypercholesterolaemia			2	(1.6)
Dyslipidaemia	1	(1.2)		
Haemochromatosis	1	(1.2)		
Glucose tolerance impaired			1	(0.8)
Hyperuricaemia			1	(0.8)
Overweight			1	(0.8)
Vitamin B12 deficiency			1	(0.8)
Musculoskeletal and connective tissue disorders				
Osteoarthritis			6	(4.8)
Back pain			4	(3.2)
Intervertebral disc protrusion			4	(3.2)
Muscle spasms			2	(1.6)
Ankylosing spondylitis	1	(1.2)		
Arthralgia	1	(1.2)	1	(0.8)
Arthritis	1	(1.2)	1	(0.8)
Joint instability	1	(1.2)		
Intervertebral disc degeneration			1	(0.8)
Intervertebral disc disorder			1	(0.8)
Joint swelling			1	(0.8)
Limb asymmetry			1	(0.8)
Neck pain			1	(0.8)
Plantar fasciitis			1	(0.8)
Rheumatoid arthritis			1	(0.8)
Scoliosis			1	(0.8)
Vertebral osteophyte			1	(0.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Skin papilloma	1	(1.2)		
Haemangioma			1	(0.8)
Leiomyoma			1	(0.8)
Lipoma			1	(0.8)
Seborrhoeic keratosis			1	(0.8)
Nervous system disorders				
Headache	1	(1.2)	5	(4.0)
Migraine			2	(1.6)
Seizure	1	(1.2)	1	(0.8)
Tension headache	1	(1.2)		
Delayed sleep phase			1	(0.8)
Diabetic neuropathy			1	(0.8)
Epilepsy			1	(0.8)
Migraine with aura			1	(0.8)
Somnolence			1	(0.8)
Psychiatric disorders				
Depression	1	(1.2)	8	(6.4)
Insomnia	1	(1.2)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.102.3.1: Total, Male, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Male				
Psychiatric disorders				
Insomnia			5	(4.0)
Autism spectrum disorder	3	(3.6)		
Anxiety	2	(2.4)	3	(2.4)
Anxiety disorder	2	(2.4)		
Depersonalisation/derealisation disorder	1	(1.2)		
Sleep disorder	1	(1.2)	1	(0.8)
Attention deficit/hyperactivity disorder			1	(0.8)
Oppositional defiant disorder			1	(0.8)
Social anxiety disorder			1	(0.8)
Renal and urinary disorders				
Renal colic	1	(1.2)		
Renal cyst	1	(1.2)	1	(0.8)
Automatic bladder			1	(0.8)
Chronic kidney disease			1	(0.8)
Reproductive system and breast disorders				
Benign prostatic hyperplasia			2	(1.6)
Erectile dysfunction	1	(1.2)	1	(0.8)
Respiratory, thoracic and mediastinal disorders				
Asthma	36	(43.4)	64	(51.2)
Rhinitis allergic	10	(12.0)	11	(8.8)
Sleep apnoea syndrome	1	(1.2)	6	(4.8)
Chronic obstructive pulmonary disease			5	(4.0)
Rhinitis perennial	1	(1.2)		
Lung cyst			1	(0.8)
Skin and subcutaneous tissue disorders				
Vitiligo	4	(4.8)		
Androgenetic alopecia	3	(3.6)	3	(2.4)
Acne			4	(3.2)
Alopecia areata	2	(2.4)	2	(1.6)
Alopecia	1	(1.2)	1	(0.8)
Dermal cyst	1	(1.2)		
Dermatitis papillaris capillitii	1	(1.2)		
Neurodermatitis	1	(1.2)	1	(0.8)
Dermatitis contact			1	(0.8)
Keratosis pilaris			1	(0.8)
Urticaria			1	(0.8)
Social circumstances				
Tobacco user	2	(2.4)	2	(1.6)
Surgical and medical procedures				
Immune tolerance induction	1	(1.2)		
Osteosynthesis	1	(1.2)		
Vasectomy	1	(1.2)		
Cataract operation			1	(0.8)
Continuous positive airway pressure			1	(0.8)
Corneal transplant			1	(0.8)
Keratoplasty			1	(0.8)
Knee arthroplasty			1	(0.8)
Vascular disorders				
Hypertension	9	(10.8)	24	(19.2)
Peripheral vascular disorder			2	(1.6)
Poor peripheral circulation			1	(0.8)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.102.3.1: Total, Female, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Female				
Analysis set				
N	43		127	
Blood and lymphatic system disorders				
Anaemia			7	(5.5)
Lymphadenopathy	1	(2.3)		
Hypercoagulation			1	(0.8)
Iron deficiency anaemia			1	(0.8)
Leukocytosis			1	(0.8)
Cardiac disorders				
Bundle branch block right	1	(2.3)	1	(0.8)
Bundle branch block left			1	(0.8)
Congenital, familial and genetic disorders				
Congenital naevus	1	(2.3)		
Ichthyosis	1	(2.3)		
Thalassaemia beta	1	(2.3)		
Arrhythmogenic right ventricular dysplasia			1	(0.8)
Type V hyperlipidaemia			1	(0.8)
Ear and labyrinth disorders				
Deafness unilateral	1	(2.3)		
Hyperacusis	1	(2.3)		
Vertigo positional	1	(2.3)		
Deafness			1	(0.8)
Vertigo			1	(0.8)
Endocrine disorders				
Hypothyroidism	2	(4.7)	8	(6.3)
Autoimmune thyroiditis			2	(1.6)
Basedow's disease			1	(0.8)
Hyperthyroidism			1	(0.8)
Thyroid mass			1	(0.8)
Eye disorders				
Conjunctivitis allergic	10	(23.3)	27	(21.3)
Atopic keratoconjunctivitis	3	(7.0)	3	(2.4)
Blindness unilateral	1	(2.3)		
Visual impairment	1	(2.3)		
Myopia			2	(1.6)
Presbyopia			2	(1.6)
Astigmatism			1	(0.8)
Blepharitis			1	(0.8)
Corneal opacity			1	(0.8)
Dry eye			1	(0.8)
Eczema eyelids			1	(0.8)
Eyelid oedema			1	(0.8)
Glaucoma			1	(0.8)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	4	(9.3)	8	(6.3)
Dyspepsia	3	(7.0)	2	(1.6)
Gastritis	2	(4.7)	1	(0.8)
Colitis ulcerative	1	(2.3)		
Constipation	1	(2.3)	2	(1.6)
Diarrhoea	1	(2.3)		
Dysphagia	1	(2.3)		
Hiatus hernia	1	(2.3)		
Irritable bowel syndrome	1	(2.3)	1	(0.8)
Pancreatic cyst	1	(2.3)		
Crohn's disease			1	(0.8)
Diverticulum			1	(0.8)
Large intestine polyp			1	(0.8)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.102.3.1: Total, Female, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Female				
Gastrointestinal disorders				
Nausea			1	(0.8)
Stress ulcer			1	(0.8)
Tooth malformation			1	(0.8)
General disorders and administration site conditions				
Fatigue	1	(2.3)		
Pain			1	(0.8)
Immune system disorders				
Seasonal allergy	14	(32.6)	62	(48.8)
Food allergy	12	(27.9)	42	(33.1)
Drug hypersensitivity	6	(14.0)	15	(11.8)
Hypersensitivity			9	(7.1)
Rubber sensitivity	3	(7.0)	3	(2.4)
Sensitisation	2	(4.7)		
Multiple allergies	1	(2.3)	5	(3.9)
Allergy to animal			4	(3.1)
Allergy to chemicals	1	(2.3)	4	(3.1)
Mite allergy			3	(2.4)
Allergy to metals	1	(2.3)	2	(1.6)
Perfume sensitivity	1	(2.3)		
Allergy to arthropod sting			2	(1.6)
Dust allergy			2	(1.6)
Iodine allergy			1	(0.8)
Milk allergy			1	(0.8)
Mycotic allergy			1	(0.8)
Infections and infestations				
Herpes simplex	3	(7.0)	5	(3.9)
Oral herpes	1	(2.3)	4	(3.1)
Chronic sinusitis	1	(2.3)	1	(0.8)
Eczema herpeticum	1	(2.3)		
Hordeolum	1	(2.3)		
Rhinitis			2	(1.6)
Conjunctivitis			1	(0.8)
Conjunctivitis bacterial			1	(0.8)
Onychomycosis			1	(0.8)
Paronychia			1	(0.8)
Urinary tract infection			1	(0.8)
Viral upper respiratory tract infection			1	(0.8)
Injury, poisoning and procedural complications				
Muscle strain	1	(2.3)		
Joint injury			1	(0.8)
Ligament sprain			1	(0.8)
Limb injury			1	(0.8)
Tibia fracture			1	(0.8)
Investigations				
Blood cholesterol increased	1	(2.3)		
Blood immunoglobulin E increased			1	(0.8)
Gamma-glutamyltransferase increased			1	(0.8)
Hepatic enzyme increased			1	(0.8)
Human papilloma virus test			1	(0.8)
Human papilloma virus test positive			1	(0.8)
Low density lipoprotein increased			1	(0.8)
Vitamin D decreased			1	(0.8)
Metabolism and nutrition disorders				
Obesity	4	(9.3)	8	(6.3)
Hypercholesterolaemia	2	(4.7)	9	(7.1)
Hyperlipidaemia	2	(4.7)	6	(4.7)
Type 2 diabetes mellitus	2	(4.7)		

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Table 1.4.102.3.1: Total, Female, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Female				
Metabolism and nutrition disorders				
Type 2 diabetes mellitus			6	(4.7)
Decreased appetite	1	(2.3)	1	(0.8)
Folate deficiency	1	(2.3)		
Hypertriglyceridaemia	1	(2.3)	2	(1.6)
Lactose intolerance	1	(2.3)	1	(0.8)
Vitamin D deficiency			2	(1.6)
Cow's milk intolerance			1	(0.8)
Fructose intolerance			1	(0.8)
Gout			1	(0.8)
Hyperuricaemia			1	(0.8)
Hypoglycaemia			1	(0.8)
Hypokalaemia			1	(0.8)
Iodine deficiency			1	(0.8)
Musculoskeletal and connective tissue disorders				
Osteoarthritis	3	(7.0)	5	(3.9)
Back pain	2	(4.7)	6	(4.7)
Arthralgia	1	(2.3)	4	(3.1)
Fibromyalgia	1	(2.3)		
Intervertebral disc degeneration	1	(2.3)		
Neck pain	1	(2.3)		
Pain in extremity	1	(2.3)		
Plantar fasciitis	1	(2.3)		
Psoriatic arthropathy	1	(2.3)		
Rotator cuff syndrome	1	(2.3)		
Systemic lupus erythematosus	1	(2.3)		
Arthritis			2	(1.6)
Intervertebral disc protrusion			2	(1.6)
Scoliosis			2	(1.6)
Ankylosing spondylitis			1	(0.8)
Bursitis			1	(0.8)
Costochondritis			1	(0.8)
Haemarthrosis			1	(0.8)
Muscle tightness			1	(0.8)
Muscular weakness			1	(0.8)
Neuropathic arthropathy			1	(0.8)
Osteonecrosis			1	(0.8)
Osteoporosis			1	(0.8)
Rheumatoid arthritis			1	(0.8)
Temporomandibular joint syndrome			1	(0.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acoustic neuroma	1	(2.3)		
Haemangioma	1	(2.3)		
Seborrhoeic keratosis			2	(1.6)
Uterine leiomyoma			1	(0.8)
Nervous system disorders				
Migraine	4	(9.3)	5	(3.9)
Headache	2	(4.7)	7	(5.5)
Cervical radiculopathy	1	(2.3)		
Carpal tunnel syndrome			2	(1.6)
Diabetic neuropathy			1	(0.8)
Dizziness			1	(0.8)
Lumbar radiculopathy			1	(0.8)
Psychiatric disorders				
Depression	2	(4.7)	16	(12.6)
Anxiety	3	(7.0)	12	(9.4)
Insomnia	2	(4.7)	7	(5.5)
Attention deficit/hyperactivity disorder	2	(4.7)	2	(1.6)
Anxiety disorder	1	(2.3)		
Body dysmorphic disorder	1	(2.3)		
Generalised anxiety disorder	1	(2.3)		

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Table 1.4.102.3.1: Total, Female, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Female				
Psychiatric disorders				
Stress	1	(2.3)		
Bulimia nervosa			1	(0.8)
Post-traumatic stress disorder			1	(0.8)
Renal and urinary disorders				
Chronic kidney disease	1	(2.3)		
Pollakiuria	1	(2.3)		
Renal cyst	1	(2.3)		
Haematuria			1	(0.8)
Renal failure			1	(0.8)
Reproductive system and breast disorders				
Cervical dysplasia	1	(2.3)		
Pelvic congestion	1	(2.3)		
Dysmenorrhoea			2	(1.6)
Ovarian cyst			1	(0.8)
Respiratory, thoracic and mediastinal disorders				
Asthma	22	(51.2)	55	(43.3)
Rhinitis allergic	5	(11.6)	12	(9.4)
Chronic obstructive pulmonary disease	4	(9.3)	2	(1.6)
Nasal polyps	1	(2.3)		
Adenoidal hypertrophy			1	(0.8)
Dyspnoea			1	(0.8)
Sleep apnoea syndrome			1	(0.8)
Vocal cord dysfunction			1	(0.8)
Skin and subcutaneous tissue disorders				
Dermatitis contact	2	(4.7)	3	(2.4)
Pruritus	2	(4.7)	1	(0.8)
Vitiligo			3	(2.4)
Alopecia	1	(2.3)	2	(1.6)
Alopecia areata	1	(2.3)	2	(1.6)
Alopecia universalis	1	(2.3)		
Chronic spontaneous urticaria	1	(2.3)	1	(0.8)
Dermal cyst	1	(2.3)	1	(0.8)
Dyshidrotic eczema	1	(2.3)		
Hyperkeratosis	1	(2.3)		
Psoriasis	1	(2.3)		
Transient acantholytic dermatosis	1	(2.3)		
Urticaria	1	(2.3)	1	(0.8)
Acne			2	(1.6)
Actinic keratosis			2	(1.6)
Acanthosis nigricans			1	(0.8)
Dry skin			1	(0.8)
Hidradenitis			1	(0.8)
Lichen sclerosus			1	(0.8)
Rosacea			1	(0.8)
Social circumstances				
Postmenopause	3	(7.0)	2	(1.6)
Tobacco user	3	(7.0)	3	(2.4)
Menopause			1	(0.8)
Surgical and medical procedures				
Alcohol rehabilitation	1	(2.3)		
Appendicectomy	1	(2.3)		
Caesarean section	1	(2.3)		
Heart valve replacement	1	(2.3)	1	(0.8)
Hip arthroplasty			1	(0.8)
Intra-uterine contraceptive device			1	(0.8)
Intra-uterine contraceptive device insertion			1	(0.8)
Vascular disorders				
Hypertension	11	(25.6)		

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Table 1.4.102.3.1: Total, Female, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Female		
Vascular disorders		
Hypertension		19 (15.0)
Lymphoedema	1 (2.3)	
Raynaud's phenomenon	1 (2.3)	
Arteriosclerosis		1 (0.8)
Deep vein thrombosis		1 (0.8)
Peripheral vascular disorder		1 (0.8)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.102.4.1: Total, Male, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Male				
Analysis set				
N	83		81	
Blood and lymphatic system disorders				
Eosinophilia			1	(1.2)
Lymphadenopathy			1	(1.2)
Lymphopenia			1	(1.2)
Normochromic normocytic anaemia	1	(1.2)		
Cardiac disorders				
Bundle branch block right	3	(3.6)		
Atrial fibrillation	1	(1.2)	2	(2.5)
Sinus bradycardia	1	(1.2)	2	(2.5)
Atrioventricular block first degree			1	(1.2)
Bundle branch block left			1	(1.2)
Congestive cardiomyopathy			1	(1.2)
Mitral valve incompetence			1	(1.2)
Atrial flutter	1	(1.2)		
Atrioventricular block	1	(1.2)		
Cardiomyopathy	1	(1.2)		
Myocardial infarction	1	(1.2)		
Myocardial ischaemia	1	(1.2)		
Congenital, familial and genetic disorders				
Gilbert's syndrome	1	(1.2)		
Ear and labyrinth disorders				
Deafness	1	(1.2)		
Deafness neurosensory	1	(1.2)		
Tinnitus	1	(1.2)		
Endocrine disorders				
Hypothyroidism			4	(4.9)
Autoimmune thyroiditis	2	(2.4)		
Thyroiditis			1	(1.2)
Eye disorders				
Conjunctivitis allergic	26	(31.3)	25	(30.9)
Atopic keratoconjunctivitis	3	(3.6)	1	(1.2)
Keratoconus	3	(3.6)		
Blepharitis			1	(1.2)
Cataract			1	(1.2)
Glaucoma			1	(1.2)
Myopia			1	(1.2)
Astigmatism	1	(1.2)		
Dry eye	1	(1.2)		
Gastrointestinal disorders				
Gastrooesophageal reflux disease	3	(3.6)	1	(1.2)
Chronic gastritis	2	(2.4)	1	(1.2)
Hiatus hernia	2	(2.4)		
Coeliac disease			1	(1.2)
Colitis ulcerative			1	(1.2)
Dyspepsia			1	(1.2)
Haemorrhoids	1	(1.2)	1	(1.2)
Irritable bowel syndrome			1	(1.2)
Barrett's oesophagus	1	(1.2)		
Crohn's disease	1	(1.2)		
Gastritis	1	(1.2)		
General disorders and administration site conditions				
Xerosis	1	(1.2)	2	(2.5)
Hernia	1	(1.2)		
Hepatobiliary disorders				
Hepatic steatosis			1	(1.2)

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Table 1.4.102.4.1: Total, Male, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Male				
Immune system disorders				
Seasonal allergy	39	(47.0)	46	(56.8)
Food allergy	30	(36.1)	31	(38.3)
Allergy to animal	11	(13.3)	5	(6.2)
Mite allergy	10	(12.0)	9	(11.1)
Multiple allergies	2	(2.4)	8	(9.9)
Drug hypersensitivity	6	(7.2)	7	(8.6)
Rubber sensitivity			4	(4.9)
Allergy to metals			2	(2.5)
Allergy to plants	2	(2.4)	2	(2.5)
Hypersensitivity	2	(2.4)	1	(1.2)
Dust allergy	1	(1.2)	1	(1.2)
Iodine allergy			1	(1.2)
Milk allergy	1	(1.2)	1	(1.2)
Flour sensitivity	1	(1.2)		
Infections and infestations				
Herpes simplex	7	(8.4)	8	(9.9)
Sinusitis	2	(2.4)	1	(1.2)
Ear infection			1	(1.2)
Epididymitis			1	(1.2)
Oral herpes			1	(1.2)
Skin candida			1	(1.2)
Onychomycosis	1	(1.2)		
Injury, poisoning and procedural complications				
Deafness traumatic	1	(1.2)		
Investigations				
Blood immunoglobulin E increased			1	(1.2)
Aspartate aminotransferase increased	1	(1.2)		
Gamma-glutamyltransferase increased	1	(1.2)		
Mean cell volume increased	1	(1.2)		
Neutrophil count increased	1	(1.2)		
Vitamin B12 decreased	1	(1.2)		
White blood cell count increased	1	(1.2)		
Metabolism and nutrition disorders				
Dyslipidaemia	3	(3.6)	1	(1.2)
Diabetes mellitus			2	(2.5)
Hypercholesterolaemia	2	(2.4)	2	(2.5)
Hyperuricaemia			2	(2.5)
Gout	2	(2.4)		
Vitamin D deficiency	2	(2.4)	1	(1.2)
Histamine intolerance			1	(1.2)
Hypertriglyceridaemia			1	(1.2)
Obesity	1	(1.2)	1	(1.2)
Purine metabolism disorder			1	(1.2)
Glucose tolerance impaired	1	(1.2)		
Gluten sensitivity	1	(1.2)		
Hyperlipidaemia	1	(1.2)		
Lactose intolerance	1	(1.2)		
Type 2 diabetes mellitus	1	(1.2)		
Musculoskeletal and connective tissue disorders				
Back pain			3	(3.7)
Arthralgia	3	(3.6)		
Intervertebral disc protrusion	2	(2.4)	1	(1.2)
Myalgia	2	(2.4)		
Ankylosing spondylitis			1	(1.2)
Foot deformity			1	(1.2)
Lumbar spinal stenosis			1	(1.2)
Spinal pain			1	(1.2)
Intervertebral disc disorder	1	(1.2)		

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Table 1.4.102.4.1: Total, Male, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Male		
Musculoskeletal and connective tissue disorders		
Joint range of motion decreased	1 (1.2)	
Osteoarthritis	1 (1.2)	
Osteopenia	1 (1.2)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Haemangioma of liver		1 (1.2)
Melanocytic naevus		1 (1.2)
Skin papilloma		1 (1.2)
Haemangioma	1 (1.2)	
Nervous system disorders		
Headache	3 (3.6)	3 (3.7)
Migraine	2 (2.4)	1 (1.2)
Hypertonia		1 (1.2)
Dysaesthesia	1 (1.2)	
Narcolepsy	1 (1.2)	
Paralysis	1 (1.2)	
Restless legs syndrome	1 (1.2)	
Psychiatric disorders		
Anxiety	1 (1.2)	3 (3.7)
Depression	1 (1.2)	2 (2.5)
Affective disorder		1 (1.2)
Attention deficit/hyperactivity disorder		1 (1.2)
Depressed mood		1 (1.2)
Sleep disorder		1 (1.2)
Stress		1 (1.2)
Renal and urinary disorders		
Proteinuria	3 (3.6)	
Nephrolithiasis		2 (2.5)
Chronic kidney disease		1 (1.2)
IgA nephropathy		1 (1.2)
Renal failure	1 (1.2)	1 (1.2)
Haematuria	1 (1.2)	
Renal disorder	1 (1.2)	
Reproductive system and breast disorders		
Benign prostatic hyperplasia	2 (2.4)	1 (1.2)
Gynaecomastia		1 (1.2)
Testicular cyst		1 (1.2)
Erectile dysfunction	1 (1.2)	
Respiratory, thoracic and mediastinal disorders		
Asthma	42 (50.6)	39 (48.1)
Rhinitis allergic	11 (13.3)	6 (7.4)
Chronic obstructive pulmonary disease		2 (2.5)
Nasal septum deviation	2 (2.4)	2 (2.5)
Bronchiectasis		1 (1.2)
Nasal turbinate hypertrophy		1 (1.2)
Sleep apnoea syndrome		1 (1.2)
Nasal polyps	1 (1.2)	
Skin and subcutaneous tissue disorders		
Acne		2 (2.5)
Alopecia areata	2 (2.4)	1 (1.2)
Photosensitivity reaction		1 (1.2)
Rosacea		1 (1.2)
Vitiligo	1 (1.2)	1 (1.2)
Alopecia	1 (1.2)	
Dermatitis contact	1 (1.2)	
Psoriasis	1 (1.2)	
Skin sensitisation	1 (1.2)	

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Table 1.4.102.4.1: Total, Male, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Male		
Surgical and medical procedures		
Cardiac pacemaker insertion		1 (1.2)
Cardiac resynchronisation therapy		1 (1.2)
Knee operation		1 (1.2)
Maxillofacial operation	1 (1.2)	
Thyroidectomy	1 (1.2)	
Vascular disorders		
Hypertension	18 (21.7)	16 (19.8)
Peripheral venous disease	2 (2.4)	1 (1.2)
Varicose vein	1 (1.2)	

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.102.4.1: Total, Female, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Female				
Analysis set				
N	54		57	
Blood and lymphatic system disorders				
Thrombocytopenia	1	(1.9)		
Iron deficiency anaemia			1	(1.8)
Cardiac disorders				
Bradycardia			1	(1.8)
Tachycardia			1	(1.8)
Congenital, familial and genetic disorders				
Benign familial haematuria	1	(1.9)		
Congenital anomaly	1	(1.9)		
Congenital cystic kidney disease	1	(1.9)		
Cytogenetic abnormality	1	(1.9)		
Sickle cell anaemia	1	(1.9)		
Von Willebrand's disease			1	(1.8)
Endocrine disorders				
Hypothyroidism	2	(3.7)	5	(8.8)
Autoimmune thyroiditis	1	(1.9)		
Thyroid mass	1	(1.9)		
Goitre			1	(1.8)
Hyperprolactinaemia			1	(1.8)
Eye disorders				
Conjunctivitis allergic	15	(27.8)	15	(26.3)
Atopic keratoconjunctivitis	6	(11.1)		
Dry eye	2	(3.7)		
Cataract			2	(3.5)
Glaucoma	1	(1.9)		
Blepharitis			1	(1.8)
Keratitis			1	(1.8)
Myopia			1	(1.8)
Photophobia			1	(1.8)
Retinal degeneration			1	(1.8)
Gastrointestinal disorders				
Gastrooesophageal reflux disease			3	(5.3)
Irritable bowel syndrome	2	(3.7)		
Oesophagitis			2	(3.5)
Coeliac disease	1	(1.9)		
Barrett's oesophagus			1	(1.8)
Dyspepsia			1	(1.8)
Gastric ulcer			1	(1.8)
Hiatus hernia			1	(1.8)
General disorders and administration site conditions				
Xerosis			2	(3.5)
Dysplasia	1	(1.9)		
Oedema peripheral	1	(1.9)		
Immune system disorders				
Seasonal allergy	31	(57.4)	30	(52.6)
Food allergy	20	(37.0)	19	(33.3)
Multiple allergies	7	(13.0)	3	(5.3)
Allergy to animal	6	(11.1)	5	(8.8)
Mite allergy	6	(11.1)	5	(8.8)
Drug hypersensitivity	3	(5.6)	5	(8.8)
Allergy to chemicals	1	(1.9)	3	(5.3)
Allergy to metals	1	(1.9)	3	(5.3)
Hypersensitivity	2	(3.7)	2	(3.5)
Allergy to plants	1	(1.9)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.102.4.1: Total, Female, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Female				
Immune system disorders				
Allergy to plants			2	(3.5)
Milk allergy			2	(3.5)
Mycotic allergy	1	(1.9)	1	(1.8)
Rubber sensitivity	1	(1.9)		
Dust allergy			1	(1.8)
Oral allergy syndrome			1	(1.8)
Perfume sensitivity			1	(1.8)
Infections and infestations				
Herpes simplex	4	(7.4)	5	(8.8)
Rhinitis			2	(3.5)
Conjunctivitis	1	(1.9)		
Oral herpes	1	(1.9)	1	(1.8)
Papilloma viral infection			1	(1.8)
Injury, poisoning and procedural complications				
Scar			2	(3.5)
Joint injury			1	(1.8)
Ligament sprain			1	(1.8)
Meniscus injury			1	(1.8)
Investigations				
Blood immunoglobulin E increased	1	(1.9)		
Lymph node palpable	1	(1.9)		
Blood uric acid increased			1	(1.8)
Gamma-glutamyltransferase increased			1	(1.8)
Metabolism and nutrition disorders				
Hypercholesterolaemia	1	(1.9)	3	(5.3)
Gluten sensitivity	2	(3.7)		
Lactose intolerance	2	(3.7)		
Diabetes mellitus			2	(3.5)
Gout	1	(1.9)		
Hyperlipidaemia	1	(1.9)	1	(1.8)
Hyperuricaemia	1	(1.9)		
Iron deficiency	1	(1.9)	1	(1.8)
Mineral deficiency	1	(1.9)		
Obesity	1	(1.9)	1	(1.8)
Hyperinsulinism			1	(1.8)
Overweight			1	(1.8)
Vitamin D deficiency			1	(1.8)
Musculoskeletal and connective tissue disorders				
Osteoarthritis	1	(1.9)	3	(5.3)
Back pain	1	(1.9)	2	(3.5)
Intervertebral disc protrusion			2	(3.5)
Osteoporosis	1	(1.9)	2	(3.5)
Growth retardation	1	(1.9)		
Osteochondrosis	1	(1.9)		
Osteopenia	1	(1.9)		
Plica syndrome	1	(1.9)		
Spinal osteoarthritis	1	(1.9)		
Temporomandibular joint syndrome	1	(1.9)		
Fibromyalgia			1	(1.8)
Muscle spasms			1	(1.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Melanocytic naevus			3	(5.3)
Blepharal papilloma			1	(1.8)
Fibroma			1	(1.8)
Nervous system disorders				
Migraine	3	(5.6)	5	(8.8)
Headache	2	(3.7)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.102.4.1: Total, Female, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Female		
Nervous system disorders		
Headache		4 (7.0)
Epilepsy	1 (1.9)	
Hydrocephalus	1 (1.9)	
Migraine with aura	1 (1.9)	
Multiple sclerosis	1 (1.9)	
Restless legs syndrome	1 (1.9)	
Hypertonia		1 (1.8)
Psychiatric disorders		
Depression	3 (5.6)	1 (1.8)
Insomnia	2 (3.7)	1 (1.8)
Anxiety		2 (3.5)
Depressed mood	1 (1.9)	1 (1.8)
Eating disorder	1 (1.9)	
Fear of injection	1 (1.9)	
Nervousness	1 (1.9)	
Sleep disorder	1 (1.9)	
Renal and urinary disorders		
Haematuria	1 (1.9)	
Incontinence	1 (1.9)	
Proteinuria	1 (1.9)	
Renal cyst	1 (1.9)	
Renal vein compression	1 (1.9)	
Reproductive system and breast disorders		
Dysmenorrhoea	1 (1.9)	1 (1.8)
Menstrual disorder	1 (1.9)	
Polycystic ovaries	1 (1.9)	
Premenstrual syndrome	1 (1.9)	
Ovarian cyst		1 (1.8)
Respiratory, thoracic and mediastinal disorders		
Asthma	32 (59.3)	23 (40.4)
Rhinitis allergic	9 (16.7)	3 (5.3)
Bronchial hyperreactivity	1 (1.9)	
Sinus disorder	1 (1.9)	
Bronchitis chronic		1 (1.8)
Dysphonia		1 (1.8)
Skin and subcutaneous tissue disorders		
Alopecia	1 (1.9)	
Alopecia areata	1 (1.9)	
Photosensitivity reaction	1 (1.9)	
Urticaria	1 (1.9)	1 (1.8)
Androgenetic alopecia		1 (1.8)
Dermatitis contact		1 (1.8)
Social circumstances		
Menopause		2 (3.5)
Postmenopause	1 (1.9)	
Surgical and medical procedures		
Female sterilisation	1 (1.9)	
Gastric bypass	1 (1.9)	
Lip lesion excision	1 (1.9)	
Nasal septal operation	1 (1.9)	
Sterilisation	1 (1.9)	
Thyroid nodule removal	1 (1.9)	
Contraception		1 (1.8)
Intra-uterine contraceptive device		1 (1.8)
Vascular disorders		
Hypertension	7 (13.0)	

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Table 1.4.102.4.1: Total, Female, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Female				
Vascular disorders				
Hypertension			7	(12.3)
Peripheral venous disease			2	(3.5)
Spider vein			1	(1.8)
Varicose vein			1	(1.8)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.103.3.1: Total, Male, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Male				
Analysis set				
N	83		125	
Blood and lymphatic system disorders				
Dermatopathic lymphadenopathy	1	(1.2)		
Cardiac disorders				
Myocardial infarction			3	(2.4)
Pericarditis			1	(0.8)
Wolff-Parkinson-White syndrome			1	(0.8)
Congenital, familial and genetic disorders				
Cryptorchism	1	(1.2)		
Phimosis	1	(1.2)		
Eye disorders				
Conjunctivitis allergic	3	(3.6)	1	(0.8)
Atopic keratoconjunctivitis	2	(2.4)		
Cataract	1	(1.2)	2	(1.6)
Blepharitis	1	(1.2)	1	(0.8)
Myopia	1	(1.2)	1	(0.8)
Retinal detachment	1	(1.2)	1	(0.8)
Dry eye			1	(0.8)
Strabismus			1	(0.8)
Gastrointestinal disorders				
Haemorrhoids	1	(1.2)	2	(1.6)
Inguinal hernia	1	(1.2)	2	(1.6)
Abdominal hernia			1	(0.8)
Gingival recession			1	(0.8)
Oesophagitis			1	(0.8)
Peptic ulcer			1	(0.8)
General disorders and administration site conditions				
Inflammation			1	(0.8)
Hepatobiliary disorders				
Cholecystitis			1	(0.8)
Hepatic steatosis			1	(0.8)
Hepatitis			1	(0.8)
Immune system disorders				
Food allergy	2	(2.4)	3	(2.4)
Seasonal allergy			3	(2.4)
Allergy to animal			2	(1.6)
Infections and infestations				
Eczema herpeticum	6	(7.2)	3	(2.4)
Impetigo	3	(3.6)	5	(4.0)
Herpes zoster	2	(2.4)	2	(1.6)
Oral herpes	2	(2.4)		
Staphylococcal skin infection	2	(2.4)		
Conjunctivitis			2	(1.6)
Cellulitis	1	(1.2)	1	(0.8)
Chronic sinusitis	1	(1.2)		
Erysipelas	1	(1.2)		
Fungal infection	1	(1.2)		
Gastrointestinal candidiasis	1	(1.2)		
Herpes simplex	1	(1.2)	1	(0.8)
Herpes virus infection	1	(1.2)		
Measles	1	(1.2)		
Molluscum contagiosum	1	(1.2)		
Osteomyelitis	1	(1.2)		
Staphylococcal infection	1	(1.2)		

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Table 1.4.103.3.1: Total, Male, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Male		
Infections and infestations		
Staphylococcal infection		1 (0.8)
Varicella	1 (1.2)	
Acne pustular		1 (0.8)
Appendicitis		1 (0.8)
Ascariasis		1 (0.8)
Body tinea		1 (0.8)
Bronchitis		1 (0.8)
Conjunctivitis bacterial		1 (0.8)
Croup infectious		1 (0.8)
External ear cellulitis		1 (0.8)
Furuncle		1 (0.8)
Keratitis viral		1 (0.8)
Oesophageal candidiasis		1 (0.8)
Otitis media		1 (0.8)
Pilonidal cyst		1 (0.8)
Tinea cruris		1 (0.8)
Tinea pedis		1 (0.8)
Viral upper respiratory tract infection		1 (0.8)
Wound infection staphylococcal		1 (0.8)
Injury, poisoning and procedural complications		
Foot fracture	2 (2.4)	
Ligament rupture	1 (1.2)	2 (1.6)
Cartilage injury	1 (1.2)	
Hand fracture	1 (1.2)	
Radius fracture	1 (1.2)	
Wrist fracture	1 (1.2)	
Concussion		1 (0.8)
Femoral neck fracture		1 (0.8)
Injury		1 (0.8)
Jaw fracture		1 (0.8)
Meniscus injury		1 (0.8)
Investigations		
Arthroscopy	2 (2.4)	1 (0.8)
Colonoscopy		2 (1.6)
Endoscopy upper gastrointestinal tract	1 (1.2)	
Blood creatinine increased		1 (0.8)
Catheterisation cardiac		1 (0.8)
Metabolism and nutrition disorders		
Protein deficiency	1 (1.2)	
Hypercholesterolaemia		1 (0.8)
Type 2 diabetes mellitus		1 (0.8)
Musculoskeletal and connective tissue disorders		
Intervertebral disc protrusion	1 (1.2)	1 (0.8)
Juvenile idiopathic arthritis	1 (1.2)	
Limb mass	1 (1.2)	
Back pain		1 (0.8)
Exostosis		1 (0.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Acanthoma	1 (1.2)	
Haemangioma	1 (1.2)	
Skin papilloma		1 (0.8)
Nervous system disorders		
Hydrocephalus	1 (1.2)	
Alcoholic seizure		1 (0.8)
Migraine		1 (0.8)
Sciatica		1 (0.8)
Psychiatric disorders		
Depression	2 (2.4)	

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Table 1.4.103.3.1: Total, Male, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Male		
Psychiatric disorders		
Depression		3 (2.4)
Anxiety		1 (0.8)
Depressed mood		1 (0.8)
Drug use disorder		1 (0.8)
Renal and urinary disorders		
Nephrolithiasis		2 (1.6)
Reproductive system and breast disorders		
Testicular retraction	1 (1.2)	
Respiratory, thoracic and mediastinal disorders		
Asthma	6 (7.2)	8 (6.4)
Nasal septum deviation	2 (2.4)	
Nasal inflammation	1 (1.2)	
Nasal polyps	1 (1.2)	
Sleep apnoea syndrome		1 (0.8)
Skin and subcutaneous tissue disorders		
Acne	1 (1.2)	
Neurodermatitis	1 (1.2)	
Urticaria	1 (1.2)	
Dyshidrotic eczema		1 (0.8)
Eczema		1 (0.8)
Hypersensitivity vasculitis		1 (0.8)
Papulopustular rosacea		1 (0.8)
Surgical and medical procedures		
Tonsillectomy	4 (4.8)	6 (4.8)
Appendicectomy	2 (2.4)	5 (4.0)
Corneal transplant	2 (2.4)	
Eye operation	2 (2.4)	
Haemorrhoid operation	2 (2.4)	1 (0.8)
Nasal septal operation	2 (2.4)	1 (0.8)
Wisdom teeth removal	2 (2.4)	1 (0.8)
Inguinal hernia repair		3 (2.4)
Knee operation	1 (1.2)	3 (2.4)
Vasectomy	1 (1.2)	3 (2.4)
Aortic bypass		2 (1.6)
Cardiac ablation		2 (1.6)
Cataract operation	1 (1.2)	2 (1.6)
Cholecystectomy		2 (1.6)
Intraocular lens implant		2 (1.6)
Ligament operation		2 (1.6)
Limb operation		2 (1.6)
Renal stone removal		2 (1.6)
Arthrodesis	1 (1.2)	
Circumcision	1 (1.2)	1 (0.8)
Cyst removal	1 (1.2)	
Endodontic procedure	1 (1.2)	
Keratoplasty	1 (1.2)	
Laser therapy	1 (1.2)	
Muscle operation	1 (1.2)	
Nasal operation	1 (1.2)	1 (0.8)
Plastic surgery	1 (1.2)	
Skin neoplasm excision	1 (1.2)	
Spinal decompression	1 (1.2)	
Steroid therapy	1 (1.2)	
Transfusion	1 (1.2)	
Turbinoplasty	1 (1.2)	
Abdominal hernia repair		1 (0.8)
Angioplasty		1 (0.8)
Bone lesion excision		1 (0.8)
Brain lobectomy		1 (0.8)

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Table 1.4.103.3.1: Total, Male, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Male		
Surgical and medical procedures		
Explorative laparotomy		1 (0.8)
Eye laser surgery		1 (0.8)
Eyelid operation		1 (0.8)
Foot operation		1 (0.8)
Fracture treatment		1 (0.8)
Gingival graft		1 (0.8)
Hepatitis immunisation		1 (0.8)
Hernia repair		1 (0.8)
Intervertebral disc operation		1 (0.8)
Keratomileusis		1 (0.8)
Meniscus operation		1 (0.8)
Myopia correction		1 (0.8)
Papilloma excision		1 (0.8)
Skin graft		1 (0.8)
Spinal laminectomy		1 (0.8)
Spinal operation		1 (0.8)
Stent placement		1 (0.8)
Strabismus correction		1 (0.8)
Tenoplasty		1 (0.8)
Toe operation		1 (0.8)
Uvulectomy		1 (0.8)
Vascular disorders		
Hypertension		1 (0.8)

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Table 1.4.103.3.1: Total, Female, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Female				
Analysis set				
N	43		127	
Blood and lymphatic system disorders				
Iron deficiency anaemia	1	(2.3)		
Cardiac disorders				
Arrhythmia			1	(0.8)
Congenital, familial and genetic disorders				
Ventricular septal defect	1	(2.3)		
Ear and labyrinth disorders				
Ear disorder	1	(2.3)		
Eye disorders				
Cataract	1	(2.3)	2	(1.6)
Keratoconus	1	(2.3)		
Gastrointestinal disorders				
Chronic gastritis	1	(2.3)		
Haemorrhoids	1	(2.3)		
Inguinal hernia	1	(2.3)		
Abdominal adhesions			1	(0.8)
Colitis			1	(0.8)
Gastrooesophageal reflux disease			1	(0.8)
Lumbar hernia			1	(0.8)
Rectal prolapse			1	(0.8)
Umbilical hernia			1	(0.8)
General disorders and administration site conditions				
Chest pain			1	(0.8)
Cyst			1	(0.8)
Fatigue			1	(0.8)
Hepatobiliary disorders				
Cholecystitis	1	(2.3)	1	(0.8)
Immune system disorders				
Food allergy	1	(2.3)		
Drug hypersensitivity			1	(0.8)
Seasonal allergy			1	(0.8)
Infections and infestations				
Appendicitis	1	(2.3)	3	(2.4)
Sinusitis			3	(2.4)
Tonsillitis			3	(2.4)
Bronchitis	1	(2.3)		
Erysipelas	1	(2.3)		
Herpes simplex	1	(2.3)	2	(1.6)
Impetigo	1	(2.3)	2	(1.6)
Peritonsillitis	1	(2.3)		
Poliomyelitis	1	(2.3)		
Oral herpes			2	(1.6)
Abscess limb			1	(0.8)
Acarodermatitis			1	(0.8)
Acute sinusitis			1	(0.8)
Adenoiditis			1	(0.8)
Cellulitis			1	(0.8)
Chronic tonsillitis			1	(0.8)
Clostridium difficile colitis			1	(0.8)
Conjunctivitis			1	(0.8)
Dermatitis infected			1	(0.8)
Eczema herpeticum			1	(0.8)

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Table 1.4.103.3.1: Total, Female, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Female				
Infections and infestations				
Furuncle			1	0.8
Herpes zoster			1	0.8
Kidney infection			1	0.8
Lyme disease			1	0.8
Neuroborreliosis			1	0.8
Papilloma viral infection			1	0.8
Pneumonia			1	0.8
Staphylococcal infection			1	0.8
Urinary tract infection bacterial			1	0.8
Vulvovaginal mycotic infection			1	0.8
Injury, poisoning and procedural complications				
Clavicle fracture	1	2.3	1	0.8
Fall	1	2.3		
Wrist fracture	1	2.3		
Upper limb fracture			2	1.6
Arthropod bite			1	0.8
Foot fracture			1	0.8
Investigations				
Blood pressure increased	1	2.3		
Colonoscopy	1	2.3		
Endoscopy			1	0.8
Hysteroscopy			1	0.8
Laparoscopy			1	0.8
Smear cervix			1	0.8
Metabolism and nutrition disorders				
Hypercholesterolaemia	1	2.3		
Musculoskeletal and connective tissue disorders				
Arthralgia	1	2.3	1	0.8
Rotator cuff syndrome	1	2.3		
Osteochondrosis			1	0.8
Pain in extremity			1	0.8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Basal cell carcinoma	1	2.3	1	0.8
Cervix carcinoma	1	2.3		
Haemangioma	1	2.3		
Meningioma	1	2.3		
Anogenital warts			1	0.8
Colon cancer			1	0.8
Dysplastic naevus			1	0.8
Lip squamous cell carcinoma			1	0.8
Osteochondroma			1	0.8
Nervous system disorders				
Cerebrovascular accident	2	4.7	1	0.8
Trigeminal neuralgia	1	2.3		
Facial paresis			1	0.8
Headache			1	0.8
Migraine			1	0.8
Pregnancy, puerperium and perinatal conditions				
Abortion			1	0.8
Abortion spontaneous			1	0.8
Ectopic pregnancy			1	0.8
Gestational hypertension			1	0.8
Psychiatric disorders				
Depression	1	2.3	2	1.6
Alcohol problem			1	0.8

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.103.3.1: Total, Female, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Female		
Renal and urinary disorders		
Glomerulonephritis		1 (0.8)
Reproductive system and breast disorders		
Menorrhagia	1 (2.3)	
Cervical dysplasia		1 (0.8)
Dysmenorrhoea		1 (0.8)
Ovarian cyst		1 (0.8)
Ovarian cyst ruptured		1 (0.8)
Uterine polyp		1 (0.8)
Respiratory, thoracic and mediastinal disorders		
Asthma		6 (4.7)
Dyspnoea		1 (0.8)
Skin and subcutaneous tissue disorders		
Urticaria	1 (2.3)	2 (1.6)
Acne		1 (0.8)
Dermatitis contact		1 (0.8)
Dyshidrotic eczema		1 (0.8)
Psoriasis		1 (0.8)
Rosacea		1 (0.8)
Social circumstances		
Infant		1 (0.8)
Postmenopause		1 (0.8)
Surgical and medical procedures		
Hysterectomy	4 (9.3)	7 (5.5)
Caesarean section	1 (2.3)	10 (7.9)
Appendicectomy	3 (7.0)	8 (6.3)
Female sterilisation	3 (7.0)	4 (3.1)
Cholecystectomy	1 (2.3)	6 (4.7)
Tonsillectomy		6 (4.7)
Knee operation	2 (4.7)	
Salpingectomy		3 (2.4)
Craniotomy	1 (2.3)	
Endometrial ablation	1 (2.3)	2 (1.6)
Eye operation	1 (2.3)	
Gastric bypass	1 (2.3)	1 (0.8)
Haemorrhoid operation	1 (2.3)	
Heart valve replacement	1 (2.3)	
Ligament operation	1 (2.3)	
Mammoplasty	1 (2.3)	
Metabolic surgery	1 (2.3)	
Open reduction of fracture	1 (2.3)	
Salpingo-oophorectomy	1 (2.3)	
Skin neoplasm excision	1 (2.3)	1 (0.8)
Spinal fusion surgery	1 (2.3)	1 (0.8)
Uterine dilation and curettage	1 (2.3)	1 (0.8)
Wisdom teeth removal	1 (2.3)	1 (0.8)
Adenoidectomy		2 (1.6)
Carpal tunnel decompression		2 (1.6)
Cataract operation		2 (1.6)
Foot operation		2 (1.6)
Nasal polypectomy		2 (1.6)
Strabismus correction		2 (1.6)
Adenotonsillectomy		1 (0.8)
Ankle arthroplasty		1 (0.8)
Ankle operation		1 (0.8)
Balneotherapy		1 (0.8)
Bone operation		1 (0.8)
Cardiac ablation		1 (0.8)
Cardiac resynchronisation therapy		1 (0.8)

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Table 1.4.103.3.1: Total, Female, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Female		
Surgical and medical procedures		
Carotid artery bypass		1 (0.8)
Colectomy		1 (0.8)
Endodontic procedure		1 (0.8)
Explorative laparotomy		1 (0.8)
Hepatitis B immunisation		1 (0.8)
Hernia hiatus repair		1 (0.8)
Hernia repair		1 (0.8)
Immunisation		1 (0.8)
Implantable defibrillator insertion		1 (0.8)
In vitro fertilisation		1 (0.8)
Incisional drainage		1 (0.8)
Lithotripsy		1 (0.8)
Myomectomy		1 (0.8)
Nasal operation		1 (0.8)
Oesophagogastric fundoplasty		1 (0.8)
Oophorectomy		1 (0.8)
Oral surgery		1 (0.8)
Osteosynthesis		1 (0.8)
Otoplasty		1 (0.8)
Ovarian cystectomy		1 (0.8)
Peritoneal adhesions division		1 (0.8)
Phototherapy		1 (0.8)
Rectal prolapse repair		1 (0.8)
Renal stone removal		1 (0.8)
Rhinoplasty		1 (0.8)
Sinus operation		1 (0.8)
Spinal operation		1 (0.8)
Splenectomy		1 (0.8)
Toe operation		1 (0.8)
Umbilical hernia repair		1 (0.8)
Vascular disorders		
Kawasaki's disease	1 (2.3)	

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Table 1.4.103.4.1: Total, Male, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Male				
Analysis set				
N	83		81	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	2	(2.4)		
Iron deficiency anaemia	1	(1.2)		
Neutropenia	1	(1.2)		
Cardiac disorders				
Myocardial ischaemia			1	(1.2)
Pericarditis			1	(1.2)
Bundle branch block left	1	(1.2)		
Cardiac failure	1	(1.2)		
Congenital, familial and genetic disorders				
Phimosis			2	(2.5)
Endocrine disorders				
Thyroid mass			1	(1.2)
Goitre	1	(1.2)		
Eye disorders				
Conjunctivitis allergic	3	(3.6)	3	(3.7)
Cataract			2	(2.5)
Atopic keratoconjunctivitis			1	(1.2)
Keratoconus			1	(1.2)
Retinal detachment			1	(1.2)
Corneal oedema	1	(1.2)		
Keratitis	1	(1.2)		
Gastrointestinal disorders				
Haemorrhoids			1	(1.2)
Inguinal hernia			1	(1.2)
Proctitis			1	(1.2)
Gastrooesophageal reflux disease	1	(1.2)		
Pancreatitis acute	1	(1.2)		
General disorders and administration site conditions				
Hernia			1	(1.2)
Hypothermia			1	(1.2)
Dysplasia	1	(1.2)		
Immune system disorders				
Seasonal allergy			2	(2.5)
Corneal graft rejection	1	(1.2)		
Hypersensitivity	1	(1.2)		
Oral allergy syndrome	1	(1.2)		
Infections and infestations				
Herpes simplex	2	(2.4)	5	(6.2)
Herpes zoster	4	(4.8)	5	(6.2)
Impetigo	5	(6.0)	3	(3.7)
Eczema herpeticum	4	(4.8)	1	(1.2)
Meningitis viral			2	(2.5)
Varicella			2	(2.5)
Appendicitis	2	(2.4)		
Meningitis	2	(2.4)		
Conjunctivitis	1	(1.2)	1	(1.2)
Groin abscess			1	(1.2)
Herpes ophthalmic			1	(1.2)
Infection parasitic			1	(1.2)
Myringitis			1	(1.2)
Otitis media			1	(1.2)
Dermatitis infected	1	(1.2)		

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Table 1.4.103.4.1: Total, Male, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Male		
Infections and infestations		
Epiglottitis	1 (1.2)	
Furuncle	1 (1.2)	
Infectious mononucleosis	1 (1.2)	
Ophthalmic herpes simplex	1 (1.2)	
Oral herpes	1 (1.2)	
Pilonidal cyst	1 (1.2)	
Staphylococcal infection	1 (1.2)	
Tinea cruris	1 (1.2)	
Tuberculosis	1 (1.2)	
Upper respiratory tract infection	1 (1.2)	
Injury, poisoning and procedural complications		
Upper limb fracture	2 (2.4)	2 (2.5)
Ankle fracture		1 (1.2)
Comminuted fracture		1 (1.2)
Facial bones fracture	1 (1.2)	1 (1.2)
Foot fracture		1 (1.2)
Ligament sprain		1 (1.2)
Limb fracture		1 (1.2)
Post-traumatic neck syndrome		1 (1.2)
Spinal fracture		1 (1.2)
Wrist fracture		1 (1.2)
Clavicle fracture	1 (1.2)	
Femur fracture	1 (1.2)	
Joint dislocation	1 (1.2)	
Joint injury	1 (1.2)	
Ligament injury	1 (1.2)	
Meniscus injury	1 (1.2)	
Multiple fractures	1 (1.2)	
Investigations		
Arthroscopy	1 (1.2)	
Biopsy lymph gland	1 (1.2)	
Skin test	1 (1.2)	
Metabolism and nutrition disorders		
Hypoproteinaemia	1 (1.2)	
Starvation	1 (1.2)	
Musculoskeletal and connective tissue disorders		
Joint contracture		1 (1.2)
Lumbar spinal stenosis		1 (1.2)
Bursitis	1 (1.2)	
Osteoarthritis	1 (1.2)	
Osteochondrosis	1 (1.2)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Anogenital warts	2 (2.4)	
Bladder transitional cell carcinoma		1 (1.2)
Hodgkin's disease		1 (1.2)
Renal cancer		1 (1.2)
Sweat gland tumour		1 (1.2)
Testis cancer		1 (1.2)
Acanthoma	1 (1.2)	
Basal cell carcinoma	1 (1.2)	
Melanocytic naevus	1 (1.2)	
Prostate cancer	1 (1.2)	
Skin papilloma	1 (1.2)	
Squamous cell carcinoma of skin	1 (1.2)	
Nervous system disorders		
Epilepsy	2 (2.4)	
Cerebral ischaemia		1 (1.2)

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Table 1.4.103.4.1: Total, Male, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Male		
Psychiatric disorders		
Depression	2 (2.4)	2 (2.5)
Adjustment disorder with depressed mood		1 (1.2)
Anxiety		1 (1.2)
Panic attack		1 (1.2)
Alcoholism	1 (1.2)	
Drug use disorder	1 (1.2)	
Insomnia	1 (1.2)	
Stress	1 (1.2)	
Renal and urinary disorders		
Renal colic		1 (1.2)
Hydronephrosis	1 (1.2)	
Nephrolithiasis	1 (1.2)	
Reproductive system and breast disorders		
Sexual dysfunction		1 (1.2)
Varicocele		1 (1.2)
Acquired phimosis	1 (1.2)	
Respiratory, thoracic and mediastinal disorders		
Asthma	1 (1.2)	7 (8.6)
Bronchospasm		1 (1.2)
Pneumothorax		1 (1.2)
Rhinitis allergic		1 (1.2)
Skin and subcutaneous tissue disorders		
Dermatitis contact	2 (2.4)	1 (1.2)
Angioedema		1 (1.2)
Purpura		1 (1.2)
Seborrhoeic dermatitis		1 (1.2)
Acne	1 (1.2)	
Acne conglobata	1 (1.2)	
Dermal cyst	1 (1.2)	
Dermatitis exfoliative	1 (1.2)	
Surgical and medical procedures		
Tonsillectomy		7 (8.6)
Appendicectomy	3 (3.6)	2 (2.5)
Cataract operation		2 (2.5)
Cyst removal		2 (2.5)
UV light therapy		2 (2.5)
Immunisation	2 (2.4)	
Arthrodesis		1 (1.2)
Circumcision		1 (1.2)
Eye operation		1 (1.2)
Fracture treatment		1 (1.2)
Knee operation		1 (1.2)
Ligament operation	1 (1.2)	1 (1.2)
Lip lesion excision		1 (1.2)
Meniscus operation	1 (1.2)	1 (1.2)
Meniscus removal		1 (1.2)
Nasal septal operation		1 (1.2)
Nephrectomy		1 (1.2)
Pleurodesis		1 (1.2)
Skin neoplasm excision		1 (1.2)
Tooth extraction		1 (1.2)
Turbinoplasty	1 (1.2)	1 (1.2)
Wisdom teeth removal	1 (1.2)	1 (1.2)
Adenoidectomy	1 (1.2)	
Cardiac ablation	1 (1.2)	
Carpal tunnel decompression	1 (1.2)	
Cholecystectomy	1 (1.2)	
Finger amputation	1 (1.2)	

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Table 1.4.103.4.1: Total, Male, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Male		
Surgical and medical procedures		
Hernia repair	1 (1.2)	
Inguinal hernia repair	1 (1.2)	
Keratoplasty	1 (1.2)	
Large intestinal polypectomy	1 (1.2)	
Myringotomy	1 (1.2)	
Oral surgery	1 (1.2)	
Pneumococcal immunisation	1 (1.2)	
Polypectomy	1 (1.2)	
Shoulder operation	1 (1.2)	
Small intestinal resection	1 (1.2)	
Spinal operation	1 (1.2)	
Stent placement	1 (1.2)	
Varicose vein operation	1 (1.2)	
Vascular disorders		
Infarction		1 (1.2)

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Table 1.4.103.4.1: Total, Female, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Female		
Analysis set		
N	54	57
Endocrine disorders		
Basedow's disease	1 (1.9)	
Eye disorders		
Cataract	1 (1.9)	1 (1.8)
Conjunctivitis allergic	1 (1.9)	
Lacrimation increased	1 (1.9)	
Keratitis		1 (1.8)
Gastrointestinal disorders		
Hiatus hernia		1 (1.8)
Intestinal obstruction		1 (1.8)
Immune system disorders		
Mite allergy		1 (1.8)
Infections and infestations		
Impetigo	5 (9.3)	2 (3.5)
Eczema herpeticum	2 (3.7)	1 (1.8)
Herpes zoster	2 (3.7)	1 (1.8)
Varicella	2 (3.7)	
Erysipelas		2 (3.5)
Herpes simplex	1 (1.9)	2 (3.5)
Enterobiasis	1 (1.9)	
Helicobacter gastritis	1 (1.9)	
Infectious mononucleosis	1 (1.9)	
Mumps	1 (1.9)	
Ophthalmic herpes simplex	1 (1.9)	
Oral herpes	1 (1.9)	
Otitis externa	1 (1.9)	
Pneumonia	1 (1.9)	
Postoperative wound infection	1 (1.9)	
Pyelonephritis	1 (1.9)	
Rhinitis	1 (1.9)	
Skin bacterial infection	1 (1.9)	
Urinary tract infection	1 (1.9)	
Bacterial infection		1 (1.8)
Cellulitis		1 (1.8)
Post procedural infection		1 (1.8)
Staphylococcal skin infection		1 (1.8)
Vaginal infection		1 (1.8)
Vulvovaginal candidiasis		1 (1.8)
Injury, poisoning and procedural complications		
Chillblains	1 (1.9)	
Hand fracture	1 (1.9)	
Humerus fracture	1 (1.9)	
Joint injury	1 (1.9)	
Ligament rupture	1 (1.9)	
Wound secretion	1 (1.9)	
Tibia fracture		1 (1.8)
Investigations		
Biopsy breast	1 (1.9)	
Metabolism and nutrition disorders		
Lactose intolerance		1 (1.8)
Musculoskeletal and connective tissue disorders		
Intervertebral disc protrusion	1 (1.9)	
Foot deformity		1 (1.8)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.4.103.4.1: Total, Female, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Female		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Benign pancreatic neoplasm	1 (1.9)	
Bowen's disease	1 (1.9)	
Breast cancer	1 (1.9)	
Papilloma	1 (1.9)	
Nervous system disorders		
Migraine	1 (1.9)	1 (1.8)
Restless legs syndrome	1 (1.9)	
Paraesthesia		1 (1.8)
Seizure		1 (1.8)
Pregnancy, puerperium and perinatal conditions		
Abortion spontaneous	1 (1.9)	
HELLP syndrome	1 (1.9)	
Psychiatric disorders		
Depression		3 (5.3)
Mood altered	1 (1.9)	
Renal and urinary disorders		
Acute kidney injury	1 (1.9)	
Nephrolithiasis	1 (1.9)	
Ureterolithiasis		1 (1.8)
Reproductive system and breast disorders		
Breast cyst	1 (1.9)	
Polycystic ovaries	1 (1.9)	
Ovarian cyst		1 (1.8)
Respiratory, thoracic and mediastinal disorders		
Rhinitis allergic	2 (3.7)	
Asthma	1 (1.9)	1 (1.8)
Maxillary sinus pseudocyst	1 (1.9)	
Pulmonary embolism		1 (1.8)
Skin and subcutaneous tissue disorders		
Alopecia		2 (3.5)
Rosacea	1 (1.9)	
Acne		1 (1.8)
Alopecia areata		1 (1.8)
Hidradenitis		1 (1.8)
Ingrowing nail		1 (1.8)
Surgical and medical procedures		
Caesarean section	3 (5.6)	3 (5.3)
Hysterectomy	2 (3.7)	3 (5.3)
Adenoidectomy	2 (3.7)	2 (3.5)
Cholecystectomy	2 (3.7)	1 (1.8)
Ligament operation	2 (3.7)	1 (1.8)
Nasal septal operation	2 (3.7)	
Abscess drainage		2 (3.5)
Tonsillectomy	1 (1.9)	2 (3.5)
Appendicectomy	1 (1.9)	1 (1.8)
Benign tumour excision	1 (1.9)	
Cyst removal	1 (1.9)	
Endometrial ablation	1 (1.9)	
Eye laser surgery	1 (1.9)	
In vitro fertilisation	1 (1.9)	
Jaw operation	1 (1.9)	
Ovarian cystectomy	1 (1.9)	
Prophylaxis	1 (1.9)	
Sinus operation	1 (1.9)	
Strabismus correction	1 (1.9)	

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Table 1.4.103.4.1: Total, Female, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Female		
Surgical and medical procedures		
Tooth extraction	1 (1.9)	
Tumour excision	1 (1.9)	
Ventriculo-peritoneal shunt	1 (1.9)	
Adrenalectomy		1 (1.8)
Amygdalotomy		1 (1.8)
Arthrodesis		1 (1.8)
Bunion operation		1 (1.8)
Carpal tunnel decompression		1 (1.8)
Cataract operation		1 (1.8)
Cervical conisation		1 (1.8)
Female genital operation		1 (1.8)
Female sterilisation		1 (1.8)
Hepatitis B immunisation		1 (1.8)
Hospitalisation		1 (1.8)
Inguinal hernia repair		1 (1.8)
Knee operation		1 (1.8)
Myopia correction		1 (1.8)
Nasal polypectomy		1 (1.8)
Nephrectomy		1 (1.8)
Oophorectomy		1 (1.8)
Thyroidectomy		1 (1.8)
Turbinoplasty		1 (1.8)
Vascular disorders		
Hypertension	1 (1.9)	
Thrombophlebitis	1 (1.9)	1 (1.8)

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Table 1.4.104.3.1: Total, Male, Atopy history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	125 (100.0)	83 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	29 (23.2)	17 (20.5)
1-3	10 (8.0)	4 (4.8)
More than 3	19 (15.2)	13 (15.7)
Never	72 (57.6)	53 (63.9)
Past	16 (12.8)	10 (12.0)
1-3	6 (4.8)	6 (7.2)
More than 3	10 (8.0)	4 (4.8)
Unknown	8 (6.4)	3 (3.6)
ASTHMA		
Current	64 (51.2)	36 (43.4)
Never	44 (35.2)	31 (37.3)
Past	17 (13.6)	16 (19.3)
ATOPIC KERATOCONJUNCTIVITIS		
Current	5 (4.0)	2 (2.4)
1-3	3 (2.4)	1 (1.2)
More than 3	2 (1.6)	1 (1.2)
Never	109 (87.2)	72 (86.7)
Past	1 (0.8)	4 (4.8)
1-3	1 (0.8)	3 (3.6)
More than 3		1 (1.2)
Unknown	10 (8.0)	5 (6.0)
ECZEMA HERPETICUM		
Current	1 (0.8)	
1-3	1 (0.8)	
Never	102 (81.6)	72 (86.7)
Past	15 (12.0)	9 (10.8)
1-3	10 (8.0)	8 (9.6)
More than 3	5 (4.0)	1 (1.2)
Unknown	7 (5.6)	2 (2.4)
FOOD ALLERGY		
Current	44 (35.2)	34 (41.0)
Never	68 (54.4)	42 (50.6)
Past	8 (6.4)	2 (2.4)
Unknown	5 (4.0)	5 (6.0)
HAY FEVER		
Current	72 (57.6)	50 (60.2)
Never	38 (30.4)	29 (34.9)
Past	11 (8.8)	2 (2.4)
Unknown	4 (3.2)	2 (2.4)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.4.104.3.1: Total, Female, Atopy history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	127 (100.0)	43 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	29 (22.8)	9 (20.9)
1-3	11 (8.7)	2 (4.7)
More than 3	18 (14.2)	7 (16.3)
Never	76 (59.8)	29 (67.4)
Past	18 (14.2)	1 (2.3)
1-3	15 (11.8)	
More than 3	3 (2.4)	1 (2.3)
Unknown	4 (3.1)	4 (9.3)
ASTHMA		
Current	55 (43.3)	22 (51.2)
Never	60 (47.2)	19 (44.2)
Past	11 (8.7)	2 (4.7)
Unknown	1 (0.8)	
ATOPIC KERATOCONJUNCTIVITIS		
Current	3 (2.4)	3 (7.0)
1-3	3 (2.4)	
More than 3		3 (7.0)
Never	119 (93.7)	38 (88.4)
Past	1 (0.8)	
1-3	1 (0.8)	
Unknown	4 (3.1)	2 (4.7)
ECZEMA HERPETICUM		
Current		1 (2.3)
More than 3		1 (2.3)
Never	116 (91.3)	40 (93.0)
Past	8 (6.3)	
1-3	8 (6.3)	
Unknown	3 (2.4)	2 (4.7)
FOOD ALLERGY		
Current	45 (35.4)	14 (32.6)
Never	77 (60.6)	27 (62.8)
Past	1 (0.8)	1 (2.3)
Unknown	4 (3.1)	1 (2.3)
HAY FEVER		
Current	69 (54.3)	18 (41.9)
Never	50 (39.4)	22 (51.2)
Past	6 (4.7)	1 (2.3)
Unknown	2 (1.6)	2 (4.7)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.4.104.4.1: Total, Male, Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	81 (100.0)	83 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	25 (30.9)	26 (31.3)
More than 3	16 (19.8)	17 (20.5)
Never	38 (46.9)	46 (55.4)
Past	15 (18.5)	10 (12.0)
More than 3	7 (8.6)	7 (8.4)
Unknown	3 (3.7)	1 (1.2)
ASTHMA		
Current	39 (48.1)	42 (50.6)
Never	34 (42.0)	37 (44.6)
Past	8 (9.9)	4 (4.8)
ATOPIC KERATOCONJUNCTIVITIS		
Current		3 (3.6)
More than 3		2 (2.4)
Never	76 (93.8)	74 (89.2)
Past	3 (3.7)	4 (4.8)
More than 3		2 (2.4)
Unknown	2 (2.5)	2 (2.4)
ECZEMA HERPETICUM		
Never	71 (87.7)	71 (85.5)
Past	8 (9.9)	10 (12.0)
More than 3	1 (1.2)	2 (2.4)
Unknown	2 (2.5)	2 (2.4)
FOOD ALLERGY		
Current	35 (43.2)	33 (39.8)
Never	44 (54.3)	47 (56.6)
Past		1 (1.2)
Unknown	2 (2.5)	2 (2.4)
HAY FEVER		
Current	46 (56.8)	44 (53.0)
Never	29 (35.8)	35 (42.2)
Past	5 (6.2)	2 (2.4)
Unknown	1 (1.2)	2 (2.4)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.4.104.4.1: Total, Female, Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	57 (100.0)	54 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	16 (28.1)	15 (27.8)
More than 3	8 (14.0)	12 (22.2)
Never	34 (59.6)	28 (51.9)
Past	7 (12.3)	11 (20.4)
More than 3	5 (8.8)	5 (9.3)
ASTHMA		
Current	23 (40.4)	32 (59.3)
Never	29 (50.9)	21 (38.9)
Past	5 (8.8)	1 (1.9)
ATOPIC KERATOCONJUNCTIVITIS		
Current		6 (11.1)
More than 3		3 (5.6)
Never	55 (96.5)	43 (79.6)
Past	1 (1.8)	5 (9.3)
More than 3		1 (1.9)
Unknown	1 (1.8)	
ECZEMA HERPETICUM		
Never	50 (87.7)	47 (87.0)
Past	6 (10.5)	5 (9.3)
More than 3	3 (5.3)	1 (1.9)
Unknown	1 (1.8)	2 (3.7)
FOOD ALLERGY		
Current	21 (36.8)	22 (40.7)
Never	34 (59.6)	30 (55.6)
Past	2 (3.5)	1 (1.9)
Unknown		1 (1.9)
HAY FEVER		
Current	30 (52.6)	33 (61.1)
Never	22 (38.6)	17 (31.5)
Past	5 (8.8)	3 (5.6)
Unknown		1 (1.9)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.4.105.3.1: Total, Male, Skin disease history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	125 (100.0)	83 (100.0)
ALOPECIA		
Current	6 (4.8)	5 (6.0)
Never	116 (92.8)	75 (90.4)
Past	2 (1.6)	1 (1.2)
Unknown	1 (0.8)	2 (2.4)
CELLULITIS		
Never	115 (92.0)	79 (95.2)
Past	6 (4.8)	4 (4.8)
1-3	5 (4.0)	3 (3.6)
More than 3	1 (0.8)	1 (1.2)
Unknown	4 (3.2)	
HERPES SIMPLEX		
Current	3 (2.4)	5 (6.0)
1-3	1 (0.8)	2 (2.4)
More than 3	2 (1.6)	3 (3.6)
Never	94 (75.2)	68 (81.9)
Past	23 (18.4)	9 (10.8)
1-3	14 (11.2)	7 (8.4)
More than 3	9 (7.2)	2 (2.4)
Unknown	5 (4.0)	1 (1.2)
IMPETIGO		
Never	91 (72.8)	69 (83.1)
Past	22 (17.6)	10 (12.0)
1-3	16 (12.8)	6 (7.2)
More than 3	6 (4.8)	4 (4.8)
Unknown	12 (9.6)	4 (4.8)
OTHER SKIN INFECTIONS		
Never	105 (84.0)	65 (78.3)
Past	15 (12.0)	12 (14.5)
Unknown	5 (4.0)	6 (7.2)
VITILIGO		
Current		4 (4.8)
Never	124 (99.2)	79 (95.2)
Unknown	1 (0.8)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.4.105.3.1: Total, Female, Skin disease history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	127 (100.0)	43 (100.0)
ALOPECIA		
Current	4 (3.1)	3 (7.0)
Never	121 (95.3)	40 (93.0)
Past	2 (1.6)	
CELLULITIS		
Never	120 (94.5)	39 (90.7)
Past	6 (4.7)	2 (4.7)
1-3	6 (4.7)	2 (4.7)
Unknown	1 (0.8)	2 (4.7)
HERPES SIMPLEX		
Current	8 (6.3)	3 (7.0)
1-3	4 (3.1)	
More than 3	4 (3.1)	3 (7.0)
Never	91 (71.7)	31 (72.1)
Past	28 (22.0)	8 (18.6)
1-3	18 (14.2)	5 (11.6)
More than 3	10 (7.9)	3 (7.0)
Unknown		1 (2.3)
IMPETIGO		
Never	110 (86.6)	38 (88.4)
Past	16 (12.6)	3 (7.0)
1-3	12 (9.4)	3 (7.0)
More than 3	4 (3.1)	
Unknown	1 (0.8)	2 (4.7)
OTHER SKIN INFECTIONS		
Never	111 (87.4)	38 (88.4)
Past	12 (9.4)	2 (4.7)
Unknown	4 (3.1)	3 (7.0)
VITILIGO		
Current	3 (2.4)	
Never	123 (96.9)	43 (100.0)
Past	1 (0.8)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.4.105.4.1: Total, Male, Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	81 (100.0)	83 (100.0)
ALOPECIA		
Current	1 (1.2)	3 (3.6)
Never	80 (98.8)	78 (94.0)
Past		1 (1.2)
Unknown		1 (1.2)
CELLULITIS		
Never	76 (93.8)	78 (94.0)
Past	1 (1.2)	5 (6.0)
Unknown	4 (4.9)	
HERPES SIMPLEX		
Current	8 (9.9)	7 (8.4)
More than 3	5 (6.2)	4 (4.8)
Never	56 (69.1)	55 (66.3)
Past	15 (18.5)	21 (25.3)
More than 3	7 (8.6)	15 (18.1)
Unknown	2 (2.5)	
IMPETIGO		
Never	66 (81.5)	60 (72.3)
Past	15 (18.5)	22 (26.5)
More than 3	4 (4.9)	10 (12.0)
Unknown		1 (1.2)
OTHER SKIN INFECTIONS		
Never	72 (88.9)	72 (86.7)
Past	4 (4.9)	9 (10.8)
Unknown	5 (6.2)	2 (2.4)
VITILIGO		
Current	1 (1.2)	1 (1.2)
Never	80 (98.8)	82 (98.8)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.4.105.4.1: Total, Female, Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	57 (100.0)	54 (100.0)
ALOPECIA		
Current	1 (1.8)	2 (3.7)
Never	53 (93.0)	52 (96.3)
Past	2 (3.5)	
Unknown	1 (1.8)	
CELLULITIS		
Never	54 (94.7)	52 (96.3)
Past	2 (3.5)	2 (3.7)
Unknown	1 (1.8)	
HERPES SIMPLEX		
Current	6 (10.5)	5 (9.3)
More than 3	2 (3.5)	4 (7.4)
Never	36 (63.2)	34 (63.0)
Past	13 (22.8)	14 (25.9)
More than 3	5 (8.8)	8 (14.8)
Unknown	2 (3.5)	1 (1.9)
IMPETIGO		
Never	42 (73.7)	39 (72.2)
Past	12 (21.1)	14 (25.9)
More than 3	4 (7.0)	3 (5.6)
Unknown	3 (5.3)	1 (1.9)
OTHER SKIN INFECTIONS		
Never	45 (78.9)	45 (83.3)
Past	8 (14.0)	6 (11.1)
Unknown	4 (7.0)	3 (5.6)
VITILIGO		
Never	55 (96.5)	54 (100.0)
Past	1 (1.8)	
Unknown	1 (1.8)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.4.107.3.1: Total, Male, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	125 (100.0)	83 (100.0)
Antibiotics		
Yes	60 (48.0)	30 (36.1)
No	60 (48.0)	46 (55.4)
Unknown	5 (4.0)	7 (8.4)
Azathioprine		
Yes	9 (7.2)	8 (9.6)
More than 12 weeks?		
Yes	4 (3.2)	7 (8.4)
No	2 (1.6)	1 (1.2)
Unknown	3 (2.4)	
Reason for discontinuation		
Inadequate efficacy	6 (4.8)	8 (9.6)
Other	1 (0.8)	
Side effects	2 (1.6)	
No	113 (90.4)	73 (88.0)
Reason for not using		
Risk of side effects	15 (12.0)	13 (15.7)
Other	98 (78.4)	60 (72.3)
Unknown	3 (2.4)	2 (2.4)
Calcineurin inhibitors		
Yes	71 (56.8)	47 (56.6)
No	49 (39.2)	32 (38.6)
Unknown	4 (3.2)	4 (4.8)
Cyclosporine		
Yes	35 (28.0)	30 (36.1)
More than 12 weeks?		
Yes	29 (23.2)	25 (30.1)
No	5 (4.0)	2 (2.4)
Unknown	1 (0.8)	3 (3.6)
Reason for discontinuation		
Inadequate efficacy	17 (13.6)	15 (18.1)
Other	9 (7.2)	9 (10.8)
Side effects	9 (7.2)	6 (7.2)
No	84 (67.2)	50 (60.2)
Reason for not using		
Contraindications	7 (5.6)	3 (3.6)
Risk of side effects	27 (21.6)	21 (25.3)
Other	50 (40.0)	26 (31.3)
Unknown	6 (4.8)	3 (3.6)
Methotrexate		
Yes	20 (16.0)	23 (27.7)
More than 12 weeks?		
Yes	11 (8.8)	12 (14.5)
No	3 (2.4)	6 (7.2)
Unknown	6 (4.8)	5 (6.0)
Reason for discontinuation		
Inadequate efficacy	8 (6.4)	9 (10.8)
Other	8 (6.4)	11 (13.3)
Side effects	4 (3.2)	3 (3.6)
No	101 (80.8)	60 (72.3)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.3.1: Total, Male, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Reason for not using		
Risk of side effects	13 (10.4)	8 (9.6)
Other	88 (70.4)	52 (62.7)
Unknown	4 (3.2)	
Monoclonal antibody/Dupilumab		
Yes	6 (4.8)	7 (8.4)
No	117 (93.6)	75 (90.4)
Unknown	1 (0.8)	1 (1.2)
Mycophenolate		
Yes	4 (3.2)	2 (2.4)
More than 12 weeks?		
Yes	1 (0.8)	1 (1.2)
Unknown	3 (2.4)	1 (1.2)
Reason for discontinuation		
Inadequate efficacy	1 (0.8)	2 (2.4)
Other	1 (0.8)	
Side effects	1 (0.8)	
No	116 (92.8)	76 (91.6)
Reason for not using		
Risk of side effects	14 (11.2)	14 (16.9)
Other	102 (81.6)	62 (74.7)
Unknown	5 (4.0)	5 (6.0)
Other immunosuppressant		
Yes	4 (3.2)	
No	117 (93.6)	79 (95.2)
Unknown	4 (3.2)	4 (4.8)
Phototherapy		
Yes	58 (46.4)	35 (42.2)
No	64 (51.2)	47 (56.6)
Unknown	3 (2.4)	1 (1.2)
Systemic steroids		
Yes	75 (60.0)	57 (68.7)
No	47 (37.6)	23 (27.7)
Unknown	3 (2.4)	3 (3.6)
Topical corticosteroids		
Yes	123 (98.4)	78 (94.0)
Highest potency		
High	68 (54.4)	35 (42.2)
Low	1 (0.8)	1 (1.2)
Moderate	23 (18.4)	20 (24.1)
Ultra high	28 (22.4)	19 (22.9)
Unknown	3 (2.4)	3 (3.6)
No	2 (1.6)	5 (6.0)
Wet wraps		
Yes	19 (15.2)	11 (13.3)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.3.1: Total, Male, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	100 (80.0)	67 (80.7)
Unknown	6 (4.8)	5 (6.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.3.1: Total, Female, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	127 (100.0)	43 (100.0)
Antibiotics		
Yes	47 (37.0)	14 (32.6)
No	78 (61.4)	28 (65.1)
Unknown	2 (1.6)	1 (2.3)
Azathioprine		
Yes	4 (3.1)	4 (9.3)
More than 12 weeks?		
Yes	1 (0.8)	1 (2.3)
No	3 (2.4)	1 (2.3)
Unknown		2 (4.7)
Reason for discontinuation		
Inadequate efficacy	3 (2.4)	1 (2.3)
Other		1 (2.3)
Side effects	1 (0.8)	2 (4.7)
No	121 (95.3)	39 (90.7)
Reason for not using		
Contraindications	3 (2.4)	2 (4.7)
Risk of side effects	12 (9.4)	3 (7.0)
Other	106 (83.5)	34 (79.1)
Unknown	2 (1.6)	
Calcineurin inhibitors		
Yes	56 (44.1)	21 (48.8)
No	65 (51.2)	22 (51.2)
Unknown	6 (4.7)	
Cyclosporine		
Yes	40 (31.5)	12 (27.9)
More than 12 weeks?		
Yes	31 (24.4)	9 (20.9)
No	8 (6.3)	2 (4.7)
Unknown	1 (0.8)	1 (2.3)
Reason for discontinuation		
Inadequate efficacy	25 (19.7)	4 (9.3)
Other	4 (3.1)	3 (7.0)
Side effects	10 (7.9)	5 (11.6)
No	84 (66.1)	29 (67.4)
Reason for not using		
Contraindications	8 (6.3)	
Risk of side effects	23 (18.1)	9 (20.9)
Other	53 (41.7)	20 (46.5)
Unknown	3 (2.4)	2 (4.7)
Methotrexate		
Yes	9 (7.1)	7 (16.3)
More than 12 weeks?		
Yes	5 (3.9)	1 (2.3)
No	2 (1.6)	3 (7.0)
Unknown	2 (1.6)	3 (7.0)
Reason for discontinuation		
Inadequate efficacy	3 (2.4)	2 (4.7)
Other	4 (3.1)	3 (7.0)
Side effects	2 (1.6)	2 (4.7)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.3.1: Total, Female, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	115 (90.6)	35 (81.4)
Reason for not using		
Contraindications	4 (3.1)	2 (4.7)
Risk of side effects	6 (4.7)	2 (4.7)
Other	105 (82.7)	31 (72.1)
Unknown	3 (2.4)	1 (2.3)
Monoclonal antibody/Dupilumab		
Yes	8 (6.3)	3 (7.0)
No	118 (92.9)	39 (90.7)
Unknown	1 (0.8)	1 (2.3)
Mycophenolate		
Yes	3 (2.4)	3 (7.0)
More than 12 weeks?		
Yes	1 (0.8)	
No	2 (1.6)	2 (4.7)
Unknown		1 (2.3)
Reason for discontinuation		
Inadequate efficacy	2 (1.6)	2 (4.7)
Other		1 (2.3)
Side effects	1 (0.8)	
No	119 (93.7)	40 (93.0)
Reason for not using		
Contraindications	3 (2.4)	2 (4.7)
Risk of side effects	11 (8.7)	2 (4.7)
Other	105 (82.7)	36 (83.7)
Unknown	5 (3.9)	
Other immunosuppressant		
Yes	2 (1.6)	
No	124 (97.6)	42 (97.7)
Unknown	1 (0.8)	1 (2.3)
Phototherapy		
Yes	64 (50.4)	17 (39.5)
No	61 (48.0)	26 (60.5)
Unknown	2 (1.6)	
Systemic steroids		
Yes	72 (56.7)	28 (65.1)
No	53 (41.7)	14 (32.6)
Unknown	2 (1.6)	1 (2.3)
Topical corticosteroids		
Yes	127 (100.0)	43 (100.0)
Highest potency		
High	63 (49.6)	22 (51.2)
Low	5 (3.9)	
Moderate	25 (19.7)	9 (20.9)
Ultra high	27 (21.3)	10 (23.3)
Unknown	7 (5.5)	2 (4.7)
Wet wraps		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.3.1: Total, Female, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	15 (11.8)	4 (9.3)
No	106 (83.5)	38 (88.4)
Unknown	6 (4.7)	1 (2.3)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.4.1: Total, Male, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	81 (100.0)	83 (100.0)
Antibiotics		
Yes	35 (43.2)	43 (51.8)
No	43 (53.1)	36 (43.4)
Unknown	3 (3.7)	4 (4.8)
Azathioprine		
Yes	13 (16.0)	14 (16.9)
More than 12 weeks?		
Yes	9 (11.1)	10 (12.0)
No	3 (3.7)	2 (2.4)
Unknown	1 (1.2)	2 (2.4)
Reason for discontinuation		
Inadequate efficacy	8 (9.9)	12 (14.5)
Other	1 (1.2)	1 (1.2)
Side effects	4 (4.9)	1 (1.2)
No	63 (77.8)	66 (79.5)
Reason for not using		
Contraindications	2 (2.5)	4 (4.8)
Risk of side effects	23 (28.4)	19 (22.9)
Other	38 (46.9)	43 (51.8)
Unknown	5 (6.2)	3 (3.6)
Cyclosporine		
Yes	61 (75.3)	62 (74.7)
More than 12 weeks?		
Yes	43 (53.1)	47 (56.6)
No	18 (22.2)	15 (18.1)
Reason for discontinuation		
Treatment duration >	4 (4.9)	7 (8.4)
Inadequate efficacy	32 (39.5)	25 (30.1)
Other	4 (4.9)	4 (4.8)
Side effects	21 (25.9)	26 (31.3)
No	20 (24.7)	21 (25.3)
Reason for not using		
Contraindications	17 (21.0)	14 (16.9)
Risk of side effects	1 (1.2)	2 (2.4)
Other	2 (2.5)	5 (6.0)
Methotrexate		
Yes	12 (14.8)	19 (22.9)
More than 12 weeks?		
Yes	10 (12.3)	12 (14.5)
No	2 (2.5)	6 (7.2)
Unknown		1 (1.2)
Reason for discontinuation		
Inadequate efficacy	8 (9.9)	14 (16.9)
Other	1 (1.2)	2 (2.4)
Side effects	3 (3.7)	3 (3.6)
No	68 (84.0)	62 (74.7)
Reason for not using		
Contraindications	5 (6.2)	6 (7.2)
Risk of side effects	23 (28.4)	18 (21.7)
Other	40 (49.4)	38 (45.8)
Unknown	1 (1.2)	2 (2.4)
Monoclonal antibody/Dupilumab		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.4.1: Total, Male, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	6 (7.4)	6 (7.2)
No	74 (91.4)	76 (91.6)
Unknown	1 (1.2)	1 (1.2)
Mycophenolate		
Yes	1 (1.2)	3 (3.6)
More than 12 weeks?		
Yes	1 (1.2)	
No		3 (3.6)
Reason for discontinuation		
Inadequate efficacy	1 (1.2)	2 (2.4)
Side effects		1 (1.2)
No	75 (92.6)	77 (92.8)
Reason for not using		
Contraindications	3 (3.7)	4 (4.8)
Risk of side effects	22 (27.2)	22 (26.5)
Other	49 (60.5)	51 (61.4)
Unknown	5 (6.2)	3 (3.6)
Other immunosuppressant		
Yes	9 (11.1)	11 (13.3)
No	71 (87.7)	71 (85.5)
Unknown	1 (1.2)	1 (1.2)
Phototherapy		
Yes	51 (63.0)	56 (67.5)
No	30 (37.0)	27 (32.5)
Systemic steroids		
Yes	55 (67.9)	58 (69.9)
No	22 (27.2)	20 (24.1)
Unknown	4 (4.9)	5 (6.0)
Topical calcineurin inhibitor		
Yes	48 (59.3)	56 (67.5)
No	28 (34.6)	25 (30.1)
Unknown	5 (6.2)	2 (2.4)
Topical corticosteroids		
Yes	81 (100.0)	82 (98.8)
Highest potency		
High	47 (58.0)	30 (36.1)
Moderate	5 (6.2)	9 (10.8)
Ultra high	23 (28.4)	41 (49.4)
Unknown	6 (7.4)	2 (2.4)
No		1 (1.2)
Wet wraps		
Yes	15 (18.5)	12 (14.5)
No	61 (75.3)	69 (83.1)
Unknown	5 (6.2)	2 (2.4)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.4.1: Total, Male, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.4.1: Total, Female, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	57 (100.0)	54 (100.0)
Antibiotics		
Yes	20 (35.1)	23 (42.6)
No	33 (57.9)	26 (48.1)
Unknown	4 (7.0)	5 (9.3)
Azathioprine		
Yes	5 (8.8)	4 (7.4)
More than 12 weeks?		
Yes	4 (7.0)	2 (3.7)
No	1 (1.8)	1 (1.9)
Unknown		1 (1.9)
Reason for discontinuation		
Inadequate efficacy	4 (7.0)	2 (3.7)
Other		1 (1.9)
Side effects	1 (1.8)	1 (1.9)
No	51 (89.5)	50 (92.6)
Reason for not using		
Contraindications	3 (5.3)	6 (11.1)
Risk of side effects	21 (36.8)	14 (25.9)
Other	27 (47.4)	30 (55.6)
Unknown	1 (1.8)	
Cyclosporine		
Yes	43 (75.4)	40 (74.1)
More than 12 weeks?		
Yes	27 (47.4)	24 (44.4)
No	16 (28.1)	15 (27.8)
Unknown		1 (1.9)
Reason for discontinuation		
Treatment duration >	1 (1.8)	
Inadequate efficacy	19 (33.3)	18 (33.3)
Other	3 (5.3)	3 (5.6)
Side effects	20 (35.1)	19 (35.2)
No	14 (24.6)	14 (25.9)
Reason for not using		
Contraindications	11 (19.3)	10 (18.5)
Risk of side effects	3 (5.3)	2 (3.7)
Other		2 (3.7)
Methotrexate		
Yes	11 (19.3)	7 (13.0)
More than 12 weeks?		
Yes	5 (8.8)	6 (11.1)
No	6 (10.5)	1 (1.9)
Reason for discontinuation		
Inadequate efficacy	7 (12.3)	4 (7.4)
Side effects	4 (7.0)	3 (5.6)
No	45 (78.9)	47 (87.0)
Reason for not using		
Contraindications	6 (10.5)	6 (11.1)
Risk of side effects	16 (28.1)	14 (25.9)
Other	23 (40.4)	27 (50.0)
Unknown	1 (1.8)	
Monoclonal antibody/Dupilumab		
Yes	3 (5.3)	6 (11.1)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.4.1: Total, Female, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	53 (93.0)	48 (88.9)
Unknown	1 (1.8)	
Mycophenolate		
Yes	2 (3.5)	2 (3.7)
More than 12 weeks?		
Yes	2 (3.5)	1 (1.9)
No		1 (1.9)
Reason for discontinuation		
Inadequate efficacy	2 (3.5)	1 (1.9)
Side effects		1 (1.9)
No	52 (91.2)	52 (96.3)
Reason for not using		
Contraindications	1 (1.8)	4 (7.4)
Risk of side effects	23 (40.4)	12 (22.2)
Other	28 (49.1)	36 (66.7)
Unknown	3 (5.3)	
Other immunosuppressant		
Yes	7 (12.3)	1 (1.9)
No	49 (86.0)	52 (96.3)
Unknown	1 (1.8)	1 (1.9)
Phototherapy		
Yes	28 (49.1)	28 (51.9)
No	28 (49.1)	26 (48.1)
Unknown	1 (1.8)	
Systemic steroids		
Yes	42 (73.7)	33 (61.1)
No	14 (24.6)	19 (35.2)
Unknown	1 (1.8)	2 (3.7)
Topical calcineurin inhibitor		
Yes	44 (77.2)	39 (72.2)
No	9 (15.8)	15 (27.8)
Unknown	4 (7.0)	
Topical corticosteroids		
Yes	57 (100.0)	54 (100.0)
Highest potency		
High	29 (50.9)	24 (44.4)
Low		1 (1.9)
Moderate	5 (8.8)	6 (11.1)
Ultra high	20 (35.1)	22 (40.7)
Unknown	3 (5.3)	1 (1.9)
Wet wraps		
Yes	10 (17.5)	7 (13.0)
No	43 (75.4)	45 (83.3)
Unknown	4 (7.0)	2 (3.7)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.107.4.1: Total, Female, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.4.205.3.1: Total, Gender, EASI 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	141 (56.0)	20.2 (9.77;30.56)	1.6 (1.21; 2.03)	2.3 (1.46; 3.53)	0.0002	0.5862
Placebo + TCS	126	45 (35.7)					
Female							
Tralokinumab Q2W + TCS	127	78 (61.4)	14.4 (-2.96;31.83)	1.3 (0.93; 1.83)	1.8 (0.89; 3.65)	0.1034	
Placebo + TCS	43	20 (46.5)					
Male							
Tralokinumab Q2W + TCS	125	63 (50.4)	19.5 (6.18;32.79)	1.6 (1.13; 2.35)	2.3 (1.27; 4.09)	0.0055	
Placebo + TCS	83	25 (30.1)					

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 1.4.206.3.1: Total, Gender, EASI 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	83 (32.9)	11.4 (2.13;20.71)	1.5 (1.05; 2.25)	1.8 (1.08; 2.92)	0.0216	0.4117
Placebo + TCS	126	27 (21.4)					
Female							
Tralokinumab Q2W + TCS	127	50 (39.4)	16.1 (0.57;31.63)	1.7 (0.94; 3.05)	2.1 (0.96; 4.72)	0.0604	
Placebo + TCS	43	10 (23.3)					
Male							
Tralokinumab Q2W + TCS	125	33 (26.4)	5.5 (-6.20;17.25)	1.3 (0.76; 2.13)	1.4 (0.70; 2.64)	0.3647	
Placebo + TCS	83	17 (20.5)					

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. #: 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 1.4.209.3.1: Total, Gender, SCORAD 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	60 (23.8)	11.1 (3.16;18.98)	1.9 (1.12; 3.12)	2.1 (1.17; 3.84)	0.0117	0.6832
Placebo + TCS	126	16 (12.7)					
Female							
Tralokinumab Q2W + TCS	127	36 (28.3)	10.3 (-4.00;24.54)	1.6 (0.76; 3.32)	1.8 (0.74; 4.22)	0.1946	
Placebo + TCS	43	8 (18.6)					
Male							
Tralokinumab Q2W + TCS	125	24 (19.2)	9.5 (0.05;18.89)	2.0 (0.94; 4.16)	2.2 (0.94; 5.22)	0.0659	
Placebo + TCS	83	8 (9.6)					

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.

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Table 1.4.210.3.1: Total, Gender, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	249	115 (46.2)	9.7 (-0.74;20.16)	1.3 (0.97; 1.65)	1.5 (0.96; 2.32)	0.0738	0.6822
Placebo + TCS	126	46 (36.5)					
Female							
Tralokinumab Q2W + TCS	124	62 (50.0)	4.3 (-13.3;21.88)	1.1 (0.73; 1.65)	1.2 (0.59; 2.40)	0.6304	
Placebo + TCS	43	19 (44.2)					
Male							
Tralokinumab Q2W + TCS	125	53 (42.4)	10.5 (-2.82;23.84)	1.3 (0.91; 1.94)	1.6 (0.88; 2.81)	0.1301	
Placebo + TCS	83	27 (32.5)					

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 1.4.211.3.1: Total, Gender, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	251	153 (61.0)	17.4 (6.78;27.98)	1.4 (1.12; 1.74)	2.0 (1.30; 3.10)	0.0014	0.3938
Placebo + TCS	126	55 (43.7)					
Female							
Tralokinumab Q2W + TCS	126	80 (63.5)	8.9 (-8.70;26.47)	1.2 (0.84; 1.63)	1.4 (0.71; 2.86)	0.3110	
Placebo + TCS	43	23 (53.5)					
Male							
Tralokinumab Q2W + TCS	125	73 (58.4)	20.5 (6.92;34.11)	1.5 (1.12; 2.11)	2.3 (1.30; 4.06)	0.0039	
Placebo + TCS	83	32 (38.6)					

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 1.4.213.3.1: Total, Gender, POEM improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	250	199 (79.6)	16.2 (6.28;26.17)	1.3 (1.08; 1.46)	2.2 (1.38; 3.58)	0.0008	0.9269
Placebo + TCS	123	78 (63.4)					
Female							
Tralokinumab Q2W + TCS	127	107 (84.3)	11.8 (-3.74;27.37)	1.2 (0.94; 1.44)	1.9 (0.86; 4.37)	0.1019	
Placebo + TCS	42	30 (71.4)					
Male							
Tralokinumab Q2W + TCS	123	92 (74.8)	15.3 (2.13;28.57)	1.3 (1.02; 1.54)	2.0 (1.11; 3.71)	0.0222	
Placebo + TCS	81	48 (59.3)					

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 1.4.215.3.1: Total, Gender, DLQI 0/1, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	62 (24.6)	12.7 (4.92;20.47)	2.1 (1.23; 3.47)	2.4 (1.31; 4.43)	0.0040	0.9356
Placebo + TCS	126	15 (11.9)					
Female							
Tralokinumab Q2W + TCS	127	34 (26.8)	13.2 (-0.08;26.41)	1.9 (0.87; 4.26)	2.3 (0.88; 5.87)	0.0858	
Placebo + TCS	43	6 (14.0)					
Male							
Tralokinumab Q2W + TCS	125	28 (22.4)	11.5 (1.61;21.45)	2.1 (1.03; 4.15)	2.4 (1.05; 5.37)	0.0348	
Placebo + TCS	83	9 (10.8)					

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 1.4.273.3.1: Total, Gender, SCORAD 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	21 (8.3)	2.0 (-3.46; 7.39)	1.3 (0.60; 2.85)	1.3 (0.57; 3.14)	0.4989	0.6369
Placebo + TCS	126	8 (6.3)					
Female							
Tralokinumab Q2W + TCS	127	12 (9.4)	1.0 (-9.05;11.04)	1.1 (0.36; 3.46)	1.1 (0.33; 3.82)	0.8531	
Placebo + TCS	43	4 (9.3)					
Male							
Tralokinumab Q2W + TCS	125	9 (7.2)	2.0 (-4.45; 8.45)	1.4 (0.46; 4.25)	1.4 (0.43; 4.87)	0.5566	
Placebo + TCS	83	4 (4.8)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

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Table 1.4.276.3.1: Total, Gender, Atopic dermatitis flares, all observed data, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	75.03	70 (27.8)	119	158.60	130.5	187.5	0.7326
Placebo + TCS	126	37.94	43 (34.1)	75	197.67	155.0	244.4	0.7326
Female								
Tralokinumab Q2W + TCS	127	37.76	31 (24.4)	51	135.07	101.5	176.7	
Placebo + TCS	43	12.88	11 (25.6)	18	139.78	89.3	225.9	
Male								
Tralokinumab Q2W + TCS	125	37.28	39 (31.2)	68	182.42	142.9	230.3	
Placebo + TCS	83	25.06	32 (38.6)	57	227.41	168.4	285.8	

The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. 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. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.4.277.3.1: Total, Gender, Atopic dermatitis flares, excluding data after rescue medication, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	74.09	69 (27.4)	113	152.51	125.2	181.5	0.5289
Placebo + TCS	126	35.55	40 (31.7)	62	174.42	135.0	222.4	0.5289
Female								
Tralokinumab Q2W + TCS	127	37.68	31 (24.4)	51	135.34	101.8	177.2	
Placebo + TCS	43	12.30	11 (25.6)	15	122.00	74.4	205.4	
Male								
Tralokinumab Q2W + TCS	125	36.41	38 (30.4)	62	170.29	132.0	217.5	
Placebo + TCS	83	23.25	29 (34.9)	47	202.15	148.4	264.2	

The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. 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. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.4.279.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	126	126 7.9 (1.49)		252	251 7.7 (1.51)			
Week 16		112 4.7 (2.59)			226 3.5 (2.21)			
Week 16 chg		112 -3.1 (2.51)	-3.03 (0.21)		226 -4.1 (2.42)	-4.13 (0.15)	-1.10 (-1.61, -0.58) [-0.45 (-0.68, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.279.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	43	43 8.1 (1.37)		127	126 7.7 (1.45)			
Week 16		39 4.4 (2.43)			112 3.3 (2.15)			
Week 16 chg		39 -3.6 (2.54)	-3.32 (0.36)		112 -4.3 (2.42)	-4.44 (0.21)	-1.13 (-1.97, -0.28) [-0.46 (-0.83, -0.09)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.279.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 7.7 (1.54)		125	125 7.6 (1.58)			
Week 16		73 4.8 (2.68)			114 3.8 (2.24)			
Week 16 chg		73 -2.8 (2.46)	-2.79 (0.27)		114 -3.8 (2.39)	-3.88 (0.22)	-1.09 (-1.78, -0.41) [-0.45 (-0.75, -0.15)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.280.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)			
Week 16		112 3.7 (2.86)			226 2.4 (2.25)			
Week 16 chg		112 -3.3 (2.59)	-3.23 (0.22)		226 -4.4 (2.62)	-4.42 (0.15)	-1.19 (-1.72, -0.67) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0511
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.280.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	43	43 7.4 (1.83)		127	126 6.9 (2.06)			
Week 16		39 3.5 (2.74)			112 2.1 (2.11)			
Week 16 chg		39 -3.9 (2.73)	-3.65 (0.36)		112 -4.7 (2.54)	-4.76 (0.21)	-1.11 (-1.95, -0.27) [-0.43 (-0.80, -0.06)]	0.010

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0511
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.280.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 6.9 (2.36)		125	125 6.9 (2.20)			
Week 16		73 3.8 (2.93)			114 2.7 (2.35)			
Week 16 chg		73 -2.9 (2.47)	-2.95 (0.27)		114 -4.1 (2.68)	-4.11 (0.22)	-1.15 (-1.85, -0.46) [-0.44 (-0.74, -0.15)]	0.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0511
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.281.3.1: Total, Gender, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
SCORAD Score								
Total								
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)			
Week 16		122 40.9 (23.52)			241 29.4 (18.62)			
Week 16 chg		122 -27.7 (22.50)	-26.93 (1.75)		241 -37.4 (19.31)	-37.74 (1.24)	-10.81 (-15.0, -6.58) [-0.53 (-0.75, -0.31)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0116
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.281.3.1: Total, Gender, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	43	43 67.7 (11.29)		127	127 65.7 (12.82)		
Week 16		42 34.8 (21.24)			122 26.2 (16.58)		
Week 16 chg		42 -32.4 (22.68)	-30.42 (2.71)		122 -39.5 (18.79)	-40.13 (1.57)	-9.71 (-16.0, -3.44) 0.003 [-0.49 (-0.84, -0.13)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0116
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.281.3.1: Total, Gender, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 69.5 (14.09)		125	125 68.2 (13.62)			
Week 16		80 44.1 (24.15)			119 32.7 (20.04)			
Week 16 chg		80 -25.2 (22.15)	-24.93 (2.25)		119 -35.3 (19.69)	-35.44 (1.85)	-10.51 (-16.3, -4.75) [-0.51 (-0.80, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0116
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.282.3.1: Total, Gender, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score								
Total								
Baseline	126	125 17.2 (7.15)		252	250 17.6 (7.07)			
Week 16		120 8.3 (7.27)			239 5.7 (6.00)			
Week 16 chg		119 -8.8 (7.09)	-8.95 (0.55)		237 -11.8 (7.57)	-11.74 (0.39)	-2.78 (-4.10, -1.47) [-0.38 (-0.60, -0.15)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0217
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.282.3.1: Total, Gender, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	43	43 17.7 (7.17)		127	127 18.1 (6.86)		
Week 16		41 7.2 (6.54)			122 5.1 (5.47)		
Week 16 chg		41 -10.2 (6.97)	-10.64 (0.85)		122 -13.0 (7.43)	-12.79 (0.49)	-2.15 (-4.11, -0.19) 0.031 [-0.29 (-0.65, 0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0217
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.282.3.1: Total, Gender, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	82 17.0 (7.18)		125	123 17.1 (7.27)		
Week 16		79 8.9 (7.60)			117 6.3 (6.48)		
Week 16 chg		78 -8.0 (7.08)	-8.02 (0.71)		115 -10.7 (7.58)	-10.65 (0.59)	-2.63 (-4.45, -0.80) 0.005 [-0.36 (-0.65, -0.07)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0217
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.283.3.1: Total, Gender, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	126	124 22.4 (5.63)		252	250 22.3 (5.09)			
Week 16		120 14.6 (8.22)			239 10.4 (7.20)			
Week 16 chg		118 -7.8 (7.40)	-7.74 (0.65)		237 -11.7 (7.37)	-11.74 (0.46)	-4.00 (-5.56, -2.44) [-0.54 (-0.77, -0.32)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0190
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.283.3.1: Total, Gender, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	43	42 21.5 (5.83)		127	127 22.3 (4.96)			
Week 16		41 11.8 (7.21)			122 9.9 (6.72)			
Week 16 chg		40 -9.5 (7.03)	-9.82 (1.05)		122 -12.4 (7.27)	-12.28 (0.60)	-2.47 (-4.87, -0.07) [-0.34 (-0.70, 0.02)]	0.044

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0190
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.283.3.1: Total, Gender, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	82 22.8 (5.51)		125	123 22.3 (5.25)			
Week 16		79 16.0 (8.38)			117 11.0 (7.64)			
Week 16 chg		78 -7.0 (7.48)	-6.76 (0.83)		115 -11.0 (7.44)	-11.12 (0.68)	-4.36 (-6.48, -2.24) [-0.59 (-0.88, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0190
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.285.3.1: Total, Gender, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score											
Total											
Baseline	126	125	59.4 (23.09)			252	250	59.1 (25.01)			
Week 16		117	71.5 (21.13)				234	75.8 (18.76)			
Week 16 chg		116	12.4 (22.66)	12.50	(1.65)		232	17.0 (24.19)	16.95	(1.17)	4.45 (0.46, 8.43) 0.029 [0.19 (-0.04, 0.41)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2325
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.285.3.1: Total, Gender, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	43	43 61.4 (23.15)		127	127 60.2 (26.08)			
Week 16		40 73.7 (22.62)			118 77.7 (16.81)			
Week 16 chg		40 11.9 (24.32)	13.55 (2.77)		118 18.8 (25.09)	18.21 (1.61)	4.66 (-1.71, 11.04) [0.19 (-0.17, 0.55)]	0.151

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2325
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.285.3.1: Total, Gender, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	82 58.4 (23.13)		125	123 58.0 (23.90)		
Week 16		77 70.3 (20.37)			116 73.9 (20.45)		
Week 16 chg		76 12.6 (21.90)	12.19 (2.09)		114 15.2 (23.19)	15.43 (1.70)	3.24 (-2.09, 8.58) 0.232 [0.14 (-0.15, 0.43)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2325
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.286.3.1: Total, Gender, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss											
Total											
Baseline	126	126	6.9 (2.72)			252	252	6.5 (2.77)			
Week 16		122	3.2 (3.24)				241	2.2 (2.68)			
Week 16 chg		122	-3.7 (3.20)	-3.44	(0.25)		241	-4.2 (3.34)	-4.29	(0.18)	-0.85 (-1.45, -0.25) 0.006 [-0.26 (-0.48, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0309
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.286.3.1: Total, Gender, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	43	43 7.5 (2.16)		127	127 6.5 (2.78)			
Week 16		42 3.0 (3.13)			122 1.8 (2.46)			
Week 16 chg		42 -4.5 (3.41)	-3.86 (0.41)		122 -4.6 (3.22)	-4.86 (0.24)	-1.00 (-1.95, -0.05) [-0.31 (-0.66, 0.05)]	0.038

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0309
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.286.3.1: Total, Gender, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 6.6 (2.93)		125	125 6.4 (2.77)			
Week 16		80 3.3 (3.31)			119 2.6 (2.84)			
Week 16 chg		80 -3.2 (3.02)	-3.17 (0.31)		119 -3.7 (3.41)	-3.74 (0.26)	-0.57 (-1.37, 0.24) [-0.17 (-0.46, 0.11)]	0.167

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0309
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.291.3.1: Total, Gender, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score											
Total											
Baseline	126	126	30.4 (12.78)			252	252	28.8 (11.97)			
Week 2		124	19.8 (12.98)				251	17.0 (11.25)			
Week 2 chg		124	-10.7 (11.46)	-10.25	(0.87)		251	-11.8 (10.37)	-12.03	(0.61)	-1.78 (-3.86, 0.30) 0.094 [-0.17 (-0.38, 0.05)]
Week 4		126	16.8 (13.62)				247	13.2 (10.47)			
Week 4 chg		126	-13.6 (12.25)	-13.09	(0.86)		247	-15.8 (11.28)	-15.88	(0.61)	-2.78 (-4.86, -0.70) 0.009 [-0.24 (-0.45, -0.02)]
Week 6		125	15.2 (13.41)				247	10.7 (9.46)			
Week 6 chg		125	-15.2 (12.09)	-14.70	(0.87)		247	-18.3 (11.21)	-18.31	(0.61)	-3.62 (-5.70, -1.53) <.001 [-0.31 (-0.53, -0.10)]
Week 8		122	13.6 (12.73)				243	9.3 (8.85)			
Week 8 chg		122	-16.7 (11.39)	-15.95	(0.87)		243	-19.8 (11.30)	-19.68	(0.61)	-3.73 (-5.82, -1.64) <.001 [-0.33 (-0.55, -0.11)]
Week 10		118	13.9 (13.56)				237	8.2 (8.42)			
Week 10 chg		118	-16.2 (11.61)	-15.71	(0.87)		237	-20.7 (12.01)	-20.64	(0.62)	-4.92 (-7.03, -2.82) <.001 [-0.41 (-0.64, -0.19)]
Week 12		119	12.9 (12.82)				238	8.0 (9.27)			
Week 12 chg		119	-17.2 (11.92)	-16.57	(0.87)		238	-21.1 (12.42)	-21.12	(0.62)	-4.55 (-6.65, -2.45) <.001 [-0.37 (-0.59, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0046
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 1.4.291.3.1: Total, Gender, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	13.1 (13.79)		235	7.7 (9.25)			
Week 14 chg	118	-16.9 (13.53)	-16.27 (0.87)	235	-21.4 (12.29)	-21.30 (0.62)	-5.03 (-7.14, -2.93) [-0.40 (-0.62, -0.17)]	<.001
Week 16	123	14.1 (14.89)		241	8.1 (9.15)			
Week 16 chg	123	-16.0 (14.04)	-15.45 (0.87)	241	-20.7 (12.33)	-20.92 (0.62)	-5.47 (-7.56, -3.38) [-0.42 (-0.64, -0.20)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0046
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 1.4.291.3.1: Total, Gender, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	43	43 26.8 (10.17)		127	127 27.0 (10.83)		
Week 2		41 18.4 (12.21)			126 14.6 (9.32)		
Week 2 chg		41 -8.6 (9.44)	-8.58 (1.23)		126 -12.5 (9.65)	-12.47 (0.71)	-3.89 (-6.69, -1.08) 0.007 [-0.40 (-0.76, -0.05)]
Week 4		43 15.0 (13.12)			124 10.4 (7.08)		
Week 4 chg		43 -11.7 (11.24)	-11.98 (1.22)		124 -16.8 (10.31)	-16.47 (0.71)	-4.48 (-7.27, -1.69) 0.002 [-0.42 (-0.77, -0.08)]
Week 6		42 13.6 (14.07)			125 8.5 (6.47)		
Week 6 chg		42 -13.3 (11.77)	-13.57 (1.23)		125 -18.6 (10.59)	-18.35 (0.71)	-4.78 (-7.58, -1.98) <.001 [-0.44 (-0.79, -0.09)]
Week 8		41 11.7 (11.45)			122 7.3 (6.80)		
Week 8 chg		41 -14.7 (9.69)	-14.80 (1.23)		122 -19.9 (10.94)	-19.51 (0.71)	-4.71 (-7.52, -1.89) 0.001 [-0.44 (-0.80, -0.09)]
Week 10		41 10.8 (10.57)			120 6.2 (6.25)		
Week 10 chg		41 -15.6 (9.49)	-15.72 (1.23)		120 -21.1 (11.25)	-20.57 (0.71)	-4.86 (-7.67, -2.04) <.001 [-0.45 (-0.81, -0.09)]
Week 12		39 9.1 (9.68)			120 6.3 (7.55)		
Week 12 chg		39 -17.2 (8.43)	-17.24 (1.24)		120 -20.9 (11.50)	-20.60 (0.71)	-3.36 (-6.20, -0.52) 0.020 [-0.31 (-0.67, 0.05)]
Week 14		41 9.4 (10.94)			119 5.9 (7.26)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0046
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 1.4.291.3.1: Total, Gender, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	41	-16.9 (11.40)	-17.09 (1.23)	119	-21.3 (11.39)	-20.95 (0.72)	-3.86 (-6.68, -1.04) [-0.34 (-0.70, 0.02)]	0.007
Week 16	42	10.2 (11.20)		122	6.3 (7.44)			
Week 16 chg	42	-16.0 (10.95)	-16.14 (1.23)	122	-20.7 (11.33)	-20.52 (0.71)	-4.38 (-7.18, -1.57) [-0.39 (-0.74, -0.04)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0046
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 1.4.291.3.1: Total, Gender, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 32.3 (13.63)		125	125 30.6 (12.81)		
Week 2		83 20.5 (13.35)			125 19.5 (12.46)		
Week 2 chg		83 -11.8 (12.24)	-11.38 (1.18)		125 -11.1 (11.04)	-11.38 (0.96)	0.01 (-2.99, 3.00) 0.997 [0.00 (-0.28, 0.28)]
Week 4		83 17.7 (13.87)			123 16.0 (12.44)		
Week 4 chg		83 -14.6 (12.70)	-14.09 (1.18)		123 -14.8 (12.14)	-15.00 (0.96)	-0.91 (-3.91, 2.10) 0.553 [-0.07 (-0.35, 0.21)]
Week 6		83 16.1 (13.07)			122 12.9 (11.37)		
Week 6 chg		83 -16.2 (12.20)	-15.72 (1.18)		122 -17.9 (11.84)	-17.98 (0.97)	-2.27 (-5.27, 0.74) 0.139 [-0.19 (-0.47, 0.09)]
Week 8		81 14.7 (13.28)			121 11.3 (10.18)		
Week 8 chg		81 -17.7 (12.09)	-17.02 (1.18)		121 -19.6 (11.69)	-19.56 (0.97)	-2.55 (-5.56, 0.46) 0.097 [-0.21 (-0.50, 0.07)]
Week 10		77 15.6 (14.71)			117 10.2 (9.81)		
Week 10 chg		77 -16.6 (12.63)	-16.21 (1.19)		117 -20.2 (12.76)	-20.35 (0.97)	-4.15 (-7.18, -1.11) 0.008 [-0.33 (-0.62, -0.04)]
Week 12		80 14.8 (13.77)			118 9.7 (10.48)		
Week 12 chg		80 -17.1 (13.34)	-16.74 (1.19)		118 -21.3 (13.33)	-21.33 (0.97)	-4.59 (-7.61, -1.57) 0.003 [-0.34 (-0.63, -0.06)]
Week 14		77 15.1 (14.78)			116 9.5 (10.66)		

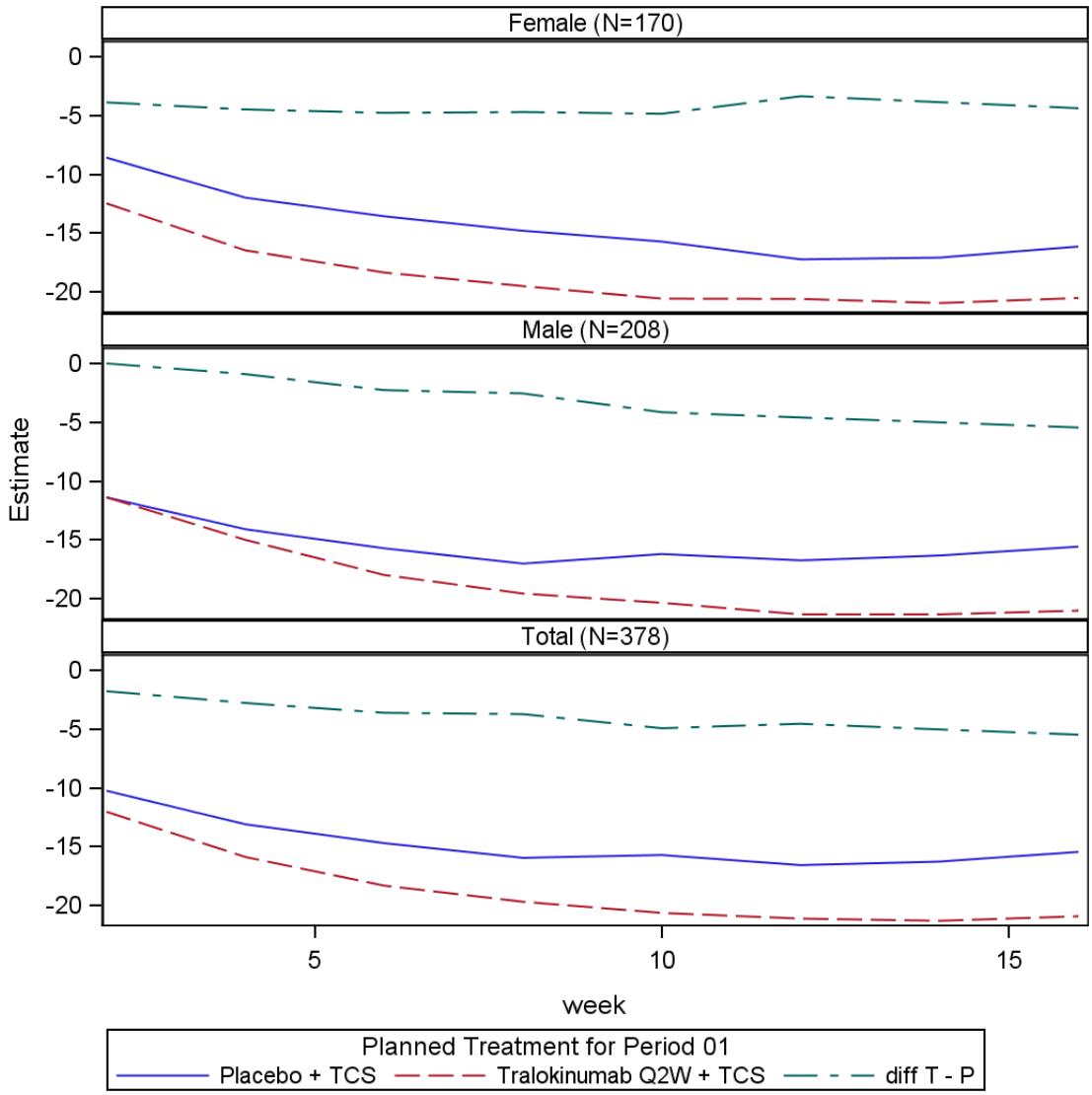
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0046
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.4.291.3.1: Total, Gender, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	77	-16.9 (14.61)	-16.33 (1.19)	116	-21.4 (13.19)	-21.34 (0.97)	-5.01 (-8.04, -1.97) [-0.36 (-0.65, -0.07)]	0.001
Week 16	81	16.1 (16.19)		119	9.9 (10.34)			
Week 16 chg	81	-16.0 (15.46)	-15.57 (1.18)	119	-20.6 (13.33)	-21.02 (0.97)	-5.44 (-8.46, -2.43) [-0.38 (-0.67, -0.10)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0046
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 1.4.291.3.2: Total, Gender, change in EASI, Treatment policy estimand, LP0162-1339, 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 1.4.293.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	126	126 7.9 (1.49)		252	251 7.7 (1.51)			
Week 1		125 6.5 (1.78)			248 6.2 (1.90)			
Week 1 chg		125 -1.3 (1.50)	-1.27 (0.19)		248 -1.5 (1.56)	-1.50 (0.14)	-0.23 (-0.69, 0.24) [-0.15 (-0.36, 0.07)]	0.336
Week 2		126 6.0 (2.11)			245 5.5 (2.23)			
Week 2 chg		126 -1.8 (2.00)	-1.80 (0.19)		245 -2.2 (2.02)	-2.19 (0.14)	-0.39 (-0.85, 0.07) [-0.19 (-0.41, 0.02)]	0.097
Week 3		125 5.8 (2.18)			243 5.0 (2.26)			
Week 3 chg		125 -2.0 (2.05)	-1.97 (0.19)		243 -2.6 (2.15)	-2.65 (0.14)	-0.68 (-1.15, -0.22) [-0.32 (-0.54, -0.11)]	0.004
Week 4		120 5.5 (2.39)			244 4.8 (2.29)			
Week 4 chg		120 -2.4 (2.21)	-2.31 (0.19)		244 -2.9 (2.21)	-2.92 (0.14)	-0.62 (-1.08, -0.15) [-0.28 (-0.50, -0.06)]	0.009
Week 5		118 5.2 (2.42)			238 4.5 (2.21)			
Week 5 chg		118 -2.7 (2.31)	-2.62 (0.19)		238 -3.2 (2.19)	-3.19 (0.14)	-0.56 (-1.03, -0.10) [-0.25 (-0.47, -0.03)]	0.018
Week 6		122 5.1 (2.50)			239 4.3 (2.23)			
Week 6 chg		122 -2.7 (2.39)	-2.68 (0.19)		239 -3.3 (2.26)	-3.30 (0.14)	-0.62 (-1.08, -0.15) [-0.27 (-0.49, -0.05)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5675
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 1.4.293.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	116	4.9 (2.48)		231	4.2 (2.27)			
Week 7 chg	116	-2.9 (2.41)	-2.79 (0.19)	231	-3.5 (2.29)	-3.47 (0.14)	-0.68 (-1.15, -0.22) [-0.29 (-0.52, -0.07)]	0.004
Week 8	116	4.9 (2.49)		227	4.0 (2.31)			
Week 8 chg	116	-2.9 (2.38)	-2.81 (0.19)	227	-3.6 (2.35)	-3.60 (0.14)	-0.79 (-1.26, -0.32) [-0.34 (-0.56, -0.11)]	<.001
Week 9	116	4.9 (2.53)		235	3.9 (2.24)			
Week 9 chg	116	-3.0 (2.35)	-2.88 (0.19)	235	-3.7 (2.31)	-3.75 (0.14)	-0.87 (-1.33, -0.40) [-0.37 (-0.60, -0.15)]	<.001
Week 10	114	4.8 (2.56)		235	3.8 (2.27)			
Week 10 chg	114	-3.0 (2.45)	-2.97 (0.19)	235	-3.8 (2.43)	-3.82 (0.14)	-0.85 (-1.31, -0.38) [-0.35 (-0.57, -0.12)]	<.001
Week 11	115	4.8 (2.54)		231	3.6 (2.19)			
Week 11 chg	115	-3.0 (2.48)	-2.96 (0.19)	231	-4.0 (2.39)	-4.03 (0.14)	-1.06 (-1.53, -0.60) [-0.44 (-0.67, -0.21)]	<.001
Week 12	115	4.7 (2.55)		234	3.7 (2.15)			
Week 12 chg	115	-3.1 (2.41)	-2.99 (0.19)	234	-3.9 (2.40)	-3.97 (0.14)	-0.98 (-1.45, -0.51) [-0.41 (-0.63, -0.18)]	<.001
Week 13	115	4.8 (2.53)		233	3.6 (2.19)			
Week 13 chg	115	-3.1 (2.37)	-3.00 (0.19)	233	-4.1 (2.44)	-4.12 (0.14)	-1.12 (-1.59, -0.65) [-0.46 (-0.69, -0.24)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5675
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 1.4.293.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	116	4.7 (2.57)		223	3.6 (2.20)			
Week 14 chg	116	-3.1 (2.42)	-3.00 (0.19)	223	-4.0 (2.49)	-4.05 (0.14)	-1.05 (-1.52, -0.58) [-0.43 (-0.65, -0.20)]	<.001
Week 15	114	4.8 (2.59)		225	3.5 (2.20)			
Week 15 chg	114	-3.0 (2.44)	-3.00 (0.19)	225	-4.1 (2.43)	-4.10 (0.14)	-1.10 (-1.57, -0.63) [-0.45 (-0.68, -0.22)]	<.001
Week 16	112	4.7 (2.59)		226	3.5 (2.21)			
Week 16 chg	112	-3.1 (2.51)	-2.99 (0.19)	226	-4.1 (2.42)	-4.12 (0.14)	-1.13 (-1.60, -0.66) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5675
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 1.4.293.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	43	43 8.1 (1.37)		127	126 7.7 (1.45)			
Week 1		43 6.5 (1.77)			125 6.0 (1.89)			
Week 1 chg		43 -1.6 (1.50)	-1.55 (0.33)		125 -1.7 (1.67)	-1.69 (0.19)	-0.14 (-0.89, 0.61) [-0.09 (-0.43, 0.26)]	0.713
Week 2		43 5.9 (2.03)			123 5.2 (2.31)			
Week 2 chg		43 -2.2 (1.93)	-2.05 (0.33)		123 -2.5 (2.18)	-2.51 (0.19)	-0.46 (-1.21, 0.30) [-0.22 (-0.56, 0.13)]	0.233
Week 3		43 5.9 (1.97)			120 4.7 (2.32)			
Week 3 chg		43 -2.2 (1.91)	-2.06 (0.33)		120 -2.9 (2.31)	-2.97 (0.19)	-0.91 (-1.66, -0.16) [-0.41 (-0.76, -0.06)]	0.018
Week 4		40 5.5 (2.24)			121 4.4 (2.32)			
Week 4 chg		40 -2.5 (2.04)	-2.41 (0.33)		121 -3.3 (2.32)	-3.28 (0.19)	-0.87 (-1.62, -0.11) [-0.38 (-0.74, -0.02)]	0.026
Week 5		38 5.0 (2.28)			122 4.1 (2.24)			
Week 5 chg		38 -3.1 (2.16)	-2.89 (0.34)		122 -3.6 (2.25)	-3.58 (0.19)	-0.69 (-1.46, 0.07) [-0.31 (-0.68, 0.05)]	0.075
Week 6		40 5.0 (2.38)			120 4.0 (2.21)			
Week 6 chg		40 -3.0 (2.25)	-2.93 (0.33)		120 -3.7 (2.30)	-3.68 (0.19)	-0.75 (-1.51, 0.01) [-0.33 (-0.69, 0.03)]	0.052
Week 7		39 4.8 (2.33)			117 3.8 (2.27)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5675
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 1.4.293.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	39	-3.2 (2.30)	-3.12 (0.33)	117	-3.8 (2.35)	-3.83 (0.19)	-0.71 (-1.47, 0.05) [-0.30 (-0.67, 0.06)]	0.068
Week 8	41	4.9 (2.39)		113	3.7 (2.25)			
Week 8 chg	41	-3.2 (2.32)	-3.07 (0.33)	113	-3.9 (2.34)	-3.96 (0.19)	-0.89 (-1.65, -0.13) [-0.38 (-0.74, -0.02)]	0.021
Week 9	40	4.7 (2.42)		117	3.7 (2.22)			
Week 9 chg	40	-3.3 (2.36)	-3.23 (0.33)	117	-4.0 (2.34)	-4.05 (0.19)	-0.82 (-1.58, -0.06) [-0.35 (-0.71, 0.01)]	0.035
Week 10	38	4.5 (2.47)		117	3.6 (2.27)			
Week 10 chg	38	-3.5 (2.56)	-3.44 (0.34)	117	-4.1 (2.46)	-4.15 (0.19)	-0.71 (-1.47, 0.06) [-0.28 (-0.65, 0.08)]	0.070
Week 11	40	4.5 (2.28)		114	3.2 (2.07)			
Week 11 chg	40	-3.6 (2.49)	-3.36 (0.33)	114	-4.4 (2.38)	-4.43 (0.19)	-1.07 (-1.83, -0.31) [-0.44 (-0.81, -0.08)]	0.006
Week 12	39	4.5 (2.30)		116	3.5 (2.08)			
Week 12 chg	39	-3.6 (2.38)	-3.34 (0.33)	116	-4.1 (2.41)	-4.26 (0.19)	-0.93 (-1.69, -0.16) [-0.38 (-0.75, -0.02)]	0.018
Week 13	38	4.6 (2.21)		117	3.3 (2.10)			
Week 13 chg	38	-3.4 (2.39)	-3.25 (0.33)	117	-4.4 (2.47)	-4.46 (0.19)	-1.21 (-1.98, -0.45) [-0.49 (-0.86, -0.12)]	0.002
Week 14	40	4.5 (2.42)		110	3.4 (2.09)			

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Test for treatment and subgroup interaction: 0.5675
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Table 1.4.293.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	40	-3.6 (2.52)	-3.34 (0.33)	110	-4.2 (2.49)	-4.32 (0.19)	-0.99 (-1.75, -0.22) 0.012 [-0.39 (-0.76, -0.03)]
Week 15	39	4.6 (2.32)		114	3.2 (2.09)		
Week 15 chg	39	-3.5 (2.46)	-3.30 (0.33)	114	-4.4 (2.46)	-4.53 (0.19)	-1.23 (-1.99, -0.47) 0.002 [-0.50 (-0.87, -0.13)]
Week 16	39	4.4 (2.43)		112	3.3 (2.15)		
Week 16 chg	39	-3.6 (2.54)	-3.39 (0.33)	112	-4.3 (2.42)	-4.48 (0.19)	-1.09 (-1.85, -0.32) 0.006 [-0.44 (-0.81, -0.07)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5675
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 1.4.293.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 7.7 (1.54)		125	125 7.6 (1.58)		
Week 1		82 6.6 (1.79)			123 6.3 (1.91)		
Week 1 chg		82 -1.2 (1.49)	-1.11 (0.23)		123 -1.3 (1.41)	-1.32 (0.19)	-0.21 (-0.80, 0.39) 0.493 [-0.14 (-0.42, 0.14)]
Week 2		83 6.1 (2.16)			122 5.8 (2.12)		
Week 2 chg		83 -1.7 (2.02)	-1.64 (0.23)		122 -1.9 (1.80)	-1.88 (0.19)	-0.23 (-0.83, 0.37) 0.447 [-0.12 (-0.40, 0.16)]
Week 3		82 5.8 (2.29)			123 5.3 (2.17)		
Week 3 chg		82 -1.9 (2.13)	-1.90 (0.23)		123 -2.3 (1.93)	-2.35 (0.19)	-0.45 (-1.05, 0.15) 0.141 [-0.22 (-0.50, 0.06)]
Week 4		80 5.5 (2.48)			123 5.1 (2.23)		
Week 4 chg		80 -2.3 (2.30)	-2.22 (0.24)		123 -2.6 (2.05)	-2.58 (0.19)	-0.35 (-0.95, 0.24) 0.246 [-0.16 (-0.45, 0.12)]
Week 5		80 5.3 (2.49)			116 4.9 (2.12)		
Week 5 chg		80 -2.5 (2.36)	-2.46 (0.24)		116 -2.8 (2.06)	-2.79 (0.19)	-0.33 (-0.93, 0.27) 0.283 [-0.15 (-0.43, 0.14)]
Week 6		82 5.2 (2.56)			119 4.7 (2.21)		
Week 6 chg		82 -2.6 (2.45)	-2.52 (0.23)		119 -3.0 (2.15)	-2.92 (0.19)	-0.40 (-1.00, 0.20) 0.187 [-0.18 (-0.46, 0.11)]
Week 7		77 5.0 (2.56)			114 4.5 (2.22)		

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Table 1.4.293.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	77	-2.7 (2.46)	-2.60 (0.24)	114	-3.2 (2.19)	-3.13 (0.19)	-0.53 (-1.13, 0.07) [-0.23 (-0.52, 0.06)]	0.084
Week 8	75	5.0 (2.57)		114	4.3 (2.35)			
Week 8 chg	75	-2.8 (2.41)	-2.65 (0.24)	114	-3.3 (2.33)	-3.25 (0.19)	-0.60 (-1.20, 0.00) [-0.25 (-0.55, 0.04)]	0.051
Week 9	76	5.0 (2.60)		118	4.2 (2.23)			
Week 9 chg	76	-2.8 (2.33)	-2.67 (0.24)	118	-3.5 (2.25)	-3.47 (0.19)	-0.79 (-1.39, -0.19) [-0.35 (-0.64, -0.06)]	0.010
Week 10	76	5.0 (2.60)		118	4.1 (2.25)			
Week 10 chg	76	-2.7 (2.37)	-2.70 (0.24)	118	-3.5 (2.38)	-3.50 (0.19)	-0.80 (-1.40, -0.20) [-0.34 (-0.63, -0.05)]	0.009
Week 11	75	4.9 (2.67)		117	4.0 (2.26)			
Week 11 chg	75	-2.8 (2.45)	-2.72 (0.24)	117	-3.7 (2.36)	-3.65 (0.19)	-0.94 (-1.54, -0.33) [-0.39 (-0.68, -0.10)]	0.002
Week 12	76	4.8 (2.68)		118	3.9 (2.20)			
Week 12 chg	76	-2.9 (2.40)	-2.77 (0.24)	118	-3.7 (2.39)	-3.71 (0.19)	-0.93 (-1.53, -0.33) [-0.39 (-0.68, -0.10)]	0.002
Week 13	77	4.9 (2.69)		116	3.8 (2.26)			
Week 13 chg	77	-2.9 (2.36)	-2.84 (0.24)	116	-3.8 (2.39)	-3.81 (0.19)	-0.97 (-1.57, -0.37) [-0.41 (-0.70, -0.12)]	0.002
Week 14	76	4.8 (2.66)		113	3.8 (2.29)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5675
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
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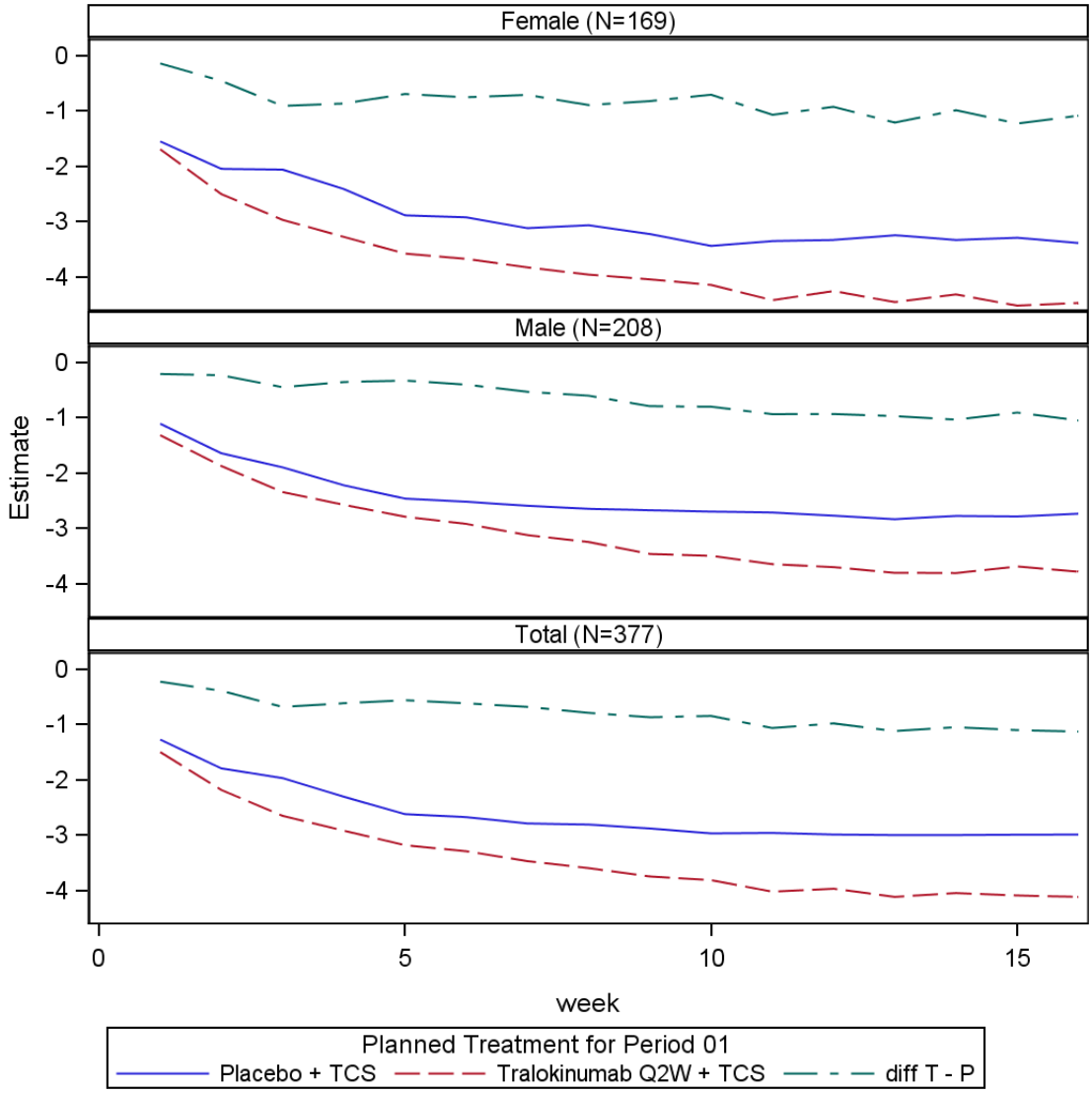
Table 1.4.293.3.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	76	-2.9 (2.34)	-2.78 (0.24)	113	-3.9 (2.48)	-3.81 (0.19)	-1.03 (-1.64, -0.43) [-0.43 (-0.72, -0.13)]	<.001
Week 15	75	4.9 (2.73)		111	3.9 (2.27)			
Week 15 chg	75	-2.8 (2.41)	-2.79 (0.24)	111	-3.8 (2.36)	-3.69 (0.19)	-0.91 (-1.51, -0.30) [-0.38 (-0.68, -0.09)]	0.003
Week 16	73	4.8 (2.68)		114	3.8 (2.24)			
Week 16 chg	73	-2.8 (2.46)	-2.74 (0.24)	114	-3.8 (2.39)	-3.79 (0.19)	-1.05 (-1.65, -0.45) [-0.43 (-0.73, -0.14)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5675
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 1.4.293.3.2: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, 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 1.4.295.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)		
Week 1		125 5.7 (2.39)			248 5.3 (2.33)		
Week 1 chg		125 -1.4 (1.62)	-1.38 (0.20)		248 -1.6 (1.68)	-1.56 (0.14)	-0.18 (-0.65, 0.30) 0.468 [-0.11 (-0.32, 0.11)]
Week 2		126 5.1 (2.66)			245 4.5 (2.54)		
Week 2 chg		126 -1.9 (2.16)	-1.90 (0.20)		245 -2.4 (2.19)	-2.35 (0.14)	-0.45 (-0.93, 0.03) 0.066 [-0.21 (-0.42, 0.01)]
Week 3		125 4.9 (2.61)			243 4.0 (2.57)		
Week 3 chg		125 -2.2 (2.17)	-2.11 (0.20)		243 -2.9 (2.33)	-2.90 (0.14)	-0.79 (-1.27, -0.31) 0.001 [-0.35 (-0.56, -0.13)]
Week 4		120 4.6 (2.69)			244 3.8 (2.59)		
Week 4 chg		120 -2.5 (2.26)	-2.44 (0.20)		244 -3.1 (2.41)	-3.15 (0.14)	-0.70 (-1.18, -0.22) 0.004 [-0.30 (-0.52, -0.08)]
Week 5		118 4.3 (2.71)			238 3.4 (2.50)		
Week 5 chg		118 -2.8 (2.32)	-2.70 (0.20)		238 -3.5 (2.40)	-3.48 (0.14)	-0.78 (-1.26, -0.30) 0.002 [-0.33 (-0.55, -0.11)]
Week 6		122 4.3 (2.76)			239 3.2 (2.50)		
Week 6 chg		122 -2.7 (2.43)	-2.70 (0.20)		239 -3.6 (2.53)	-3.61 (0.14)	-0.91 (-1.39, -0.43) <.001 [-0.36 (-0.58, -0.14)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3704
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 1.4.295.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7		116 4.0 (2.76)			231 3.0 (2.47)		
Week 7 chg		116 -3.0 (2.49)	-2.97 (0.20)		231 -3.8 (2.52)	-3.81 (0.14)	-0.84 (-1.32, -0.36) <.001 [-0.34 (-0.56, -0.11)]
Week 8		116 4.0 (2.72)			227 3.0 (2.49)		
Week 8 chg		116 -3.0 (2.48)	-2.92 (0.20)		227 -3.9 (2.52)	-3.87 (0.14)	-0.95 (-1.43, -0.47) <.001 [-0.38 (-0.60, -0.15)]
Week 9		116 3.9 (2.78)			235 2.8 (2.36)		
Week 9 chg		116 -3.1 (2.48)	-3.03 (0.20)		235 -4.1 (2.49)	-4.07 (0.14)	-1.04 (-1.52, -0.56) <.001 [-0.42 (-0.64, -0.19)]
Week 10		114 3.9 (2.81)			235 2.7 (2.40)		
Week 10 chg		114 -3.1 (2.56)	-3.09 (0.20)		235 -4.1 (2.59)	-4.11 (0.14)	-1.02 (-1.50, -0.54) <.001 [-0.40 (-0.62, -0.17)]
Week 11		115 3.8 (2.71)			231 2.6 (2.33)		
Week 11 chg		115 -3.2 (2.54)	-3.10 (0.20)		231 -4.2 (2.58)	-4.22 (0.14)	-1.12 (-1.60, -0.64) <.001 [-0.44 (-0.66, -0.21)]
Week 12		115 3.8 (2.78)			234 2.7 (2.32)		
Week 12 chg		115 -3.2 (2.59)	-3.10 (0.20)		234 -4.2 (2.61)	-4.19 (0.14)	-1.09 (-1.57, -0.61) <.001 [-0.42 (-0.64, -0.19)]
Week 13		115 3.9 (2.80)			233 2.5 (2.33)		
Week 13 chg		115 -3.2 (2.52)	-3.16 (0.20)		233 -4.4 (2.66)	-4.39 (0.14)	-1.24 (-1.72, -0.75) <.001 [-0.47 (-0.70, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3704
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 1.4.295.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	116	3.8 (2.86)		223	2.5 (2.29)			
Week 14 chg	116	-3.2 (2.61)	-3.14 (0.20)	223	-4.3 (2.69)	-4.33 (0.14)	-1.20 (-1.68, -0.72) [-0.45 (-0.68, -0.22)]	<.001
Week 15	114	3.8 (2.87)		225	2.4 (2.27)			
Week 15 chg	114	-3.2 (2.56)	-3.14 (0.20)	225	-4.4 (2.64)	-4.39 (0.14)	-1.25 (-1.73, -0.77) [-0.48 (-0.71, -0.25)]	<.001
Week 16	112	3.7 (2.86)		226	2.4 (2.25)			
Week 16 chg	112	-3.3 (2.59)	-3.19 (0.20)	226	-4.4 (2.62)	-4.39 (0.14)	-1.21 (-1.69, -0.72) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3704
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 1.4.295.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	43	43 7.4 (1.83)		127	126 6.9 (2.06)		
Week 1		43 5.6 (2.34)			125 5.1 (2.24)		
Week 1 chg		43 -1.8 (1.82)	-1.75 (0.34)		125 -1.8 (1.81)	-1.75 (0.20)	0.00 (-0.78, 0.78) 0.999 [0.00 (-0.35, 0.35)]
Week 2		43 5.1 (2.70)			123 4.1 (2.58)		
Week 2 chg		43 -2.3 (2.31)	-2.20 (0.34)		123 -2.7 (2.45)	-2.72 (0.20)	-0.52 (-1.30, 0.26) 0.189 [-0.22 (-0.56, 0.13)]
Week 3		43 5.0 (2.56)			120 3.6 (2.55)		
Week 3 chg		43 -2.5 (2.22)	-2.31 (0.34)		120 -3.3 (2.55)	-3.29 (0.20)	-0.98 (-1.76, -0.20) 0.014 [-0.40 (-0.75, -0.05)]
Week 4		40 4.6 (2.62)			121 3.3 (2.45)		
Week 4 chg		40 -2.8 (2.27)	-2.71 (0.34)		121 -3.5 (2.45)	-3.56 (0.20)	-0.86 (-1.64, -0.08) 0.031 [-0.36 (-0.72, 0.00)]
Week 5		38 4.0 (2.71)			122 3.0 (2.43)		
Week 5 chg		38 -3.3 (2.38)	-3.07 (0.34)		122 -3.9 (2.38)	-3.88 (0.20)	-0.81 (-1.60, -0.02) 0.043 [-0.34 (-0.71, 0.03)]
Week 6		40 4.1 (2.77)			120 2.8 (2.36)		
Week 6 chg		40 -3.3 (2.48)	-3.17 (0.34)		120 -4.0 (2.48)	-4.04 (0.20)	-0.87 (-1.65, -0.09) 0.030 [-0.35 (-0.71, 0.01)]
Week 7		39 3.7 (2.73)			117 2.6 (2.31)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3704
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 1.4.295.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	39	-3.6 (2.63)	-3.52 (0.34)	117	-4.1 (2.44)	-4.21 (0.20)	-0.69 (-1.47, 0.10) 0.087 [-0.28 (-0.64, 0.09)]
Week 8	41	3.8 (2.71)		113	2.6 (2.31)		
Week 8 chg	41	-3.6 (2.64)	-3.41 (0.34)	113	-4.1 (2.40)	-4.25 (0.20)	-0.83 (-1.62, -0.05) 0.037 [-0.34 (-0.70, 0.02)]
Week 9	40	3.6 (2.72)		117	2.4 (2.16)		
Week 9 chg	40	-3.8 (2.59)	-3.58 (0.34)	117	-4.4 (2.39)	-4.43 (0.20)	-0.85 (-1.63, -0.06) 0.035 [-0.35 (-0.71, 0.01)]
Week 10	38	3.5 (2.73)		117	2.4 (2.27)		
Week 10 chg	38	-3.9 (2.72)	-3.73 (0.34)	117	-4.4 (2.49)	-4.50 (0.20)	-0.77 (-1.56, 0.02) 0.055 [-0.30 (-0.67, 0.06)]
Week 11	40	3.5 (2.58)		114	2.2 (2.12)		
Week 11 chg	40	-3.9 (2.73)	-3.60 (0.34)	114	-4.6 (2.50)	-4.66 (0.20)	-1.06 (-1.84, -0.27) 0.009 [-0.41 (-0.78, -0.05)]
Week 12	39	3.5 (2.64)		116	2.4 (2.18)		
Week 12 chg	39	-3.9 (2.74)	-3.60 (0.34)	116	-4.4 (2.56)	-4.54 (0.20)	-0.94 (-1.73, -0.16) 0.019 [-0.36 (-0.73, 0.00)]
Week 13	38	3.6 (2.54)		117	2.2 (2.13)		
Week 13 chg	38	-3.8 (2.71)	-3.58 (0.34)	117	-4.6 (2.62)	-4.78 (0.20)	-1.20 (-1.98, -0.41) 0.003 [-0.45 (-0.82, -0.08)]
Week 14	40	3.5 (2.79)		110	2.2 (2.10)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3704
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 1.4.295.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg		40	-3.9 (2.85)	-3.55	(0.34)		110	-4.5 (2.59)	-4.69	(0.20)	-1.14 (-1.92, -0.35) [-0.43 (-0.79, -0.06)]	0.005
Week 15		39	3.6 (2.73)				114	2.1 (2.07)				
Week 15 chg		39	-3.8 (2.81)	-3.51	(0.34)		114	-4.7 (2.57)	-4.81	(0.20)	-1.30 (-2.09, -0.52) [-0.49 (-0.86, -0.13)]	0.001
Week 16		39	3.5 (2.74)				112	2.1 (2.11)				
Week 16 chg		39	-3.9 (2.73)	-3.62	(0.34)		112	-4.7 (2.54)	-4.78	(0.20)	-1.15 (-1.94, -0.37) [-0.45 (-0.81, -0.08)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3704
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.

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Table 1.4.295.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 6.9 (2.36)		125	125 6.9 (2.20)			
Week 1		82 5.7 (2.43)			123 5.6 (2.40)			
Week 1 chg		82 -1.2 (1.47)	-1.18 (0.24)		123 -1.4 (1.52)	-1.37 (0.20)	-0.19 (-0.81, 0.42) [-0.13 (-0.41, 0.15)]	0.536
Week 2		83 5.2 (2.65)			122 4.9 (2.46)			
Week 2 chg		83 -1.7 (2.06)	-1.72 (0.24)		122 -2.0 (1.85)	-1.98 (0.20)	-0.26 (-0.87, 0.36) [-0.13 (-0.41, 0.15)]	0.412
Week 3		82 4.9 (2.65)			123 4.4 (2.53)			
Week 3 chg		82 -2.0 (2.14)	-1.99 (0.24)		123 -2.5 (2.04)	-2.53 (0.20)	-0.54 (-1.15, 0.08) [-0.26 (-0.54, 0.02)]	0.087
Week 4		80 4.6 (2.74)			123 4.2 (2.67)			
Week 4 chg		80 -2.3 (2.24)	-2.28 (0.24)		123 -2.8 (2.31)	-2.73 (0.20)	-0.45 (-1.07, 0.16) [-0.20 (-0.48, 0.08)]	0.150
Week 5		80 4.4 (2.72)			116 3.8 (2.52)			
Week 5 chg		80 -2.5 (2.26)	-2.50 (0.24)		116 -3.1 (2.37)	-3.08 (0.20)	-0.58 (-1.20, 0.04) [-0.25 (-0.54, 0.04)]	0.065
Week 6		82 4.5 (2.76)			119 3.6 (2.57)			
Week 6 chg		82 -2.5 (2.36)	-2.44 (0.24)		119 -3.2 (2.53)	-3.18 (0.20)	-0.74 (-1.35, -0.12) [-0.30 (-0.58, -0.02)]	0.020
Week 7		77 4.1 (2.78)			114 3.5 (2.56)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3704
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 1.4.295.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	77	-2.7 (2.39)	-2.66 (0.24)	114	-3.5 (2.57)	-3.42 (0.20)	-0.75 (-1.38, -0.13) [-0.30 (-0.59, -0.01)]	0.018
Week 8	75	4.1 (2.73)		114	3.3 (2.63)			
Week 8 chg	75	-2.7 (2.36)	-2.64 (0.25)	114	-3.6 (2.61)	-3.49 (0.20)	-0.85 (-1.48, -0.23) [-0.34 (-0.63, -0.05)]	0.007
Week 9	76	4.1 (2.82)		118	3.2 (2.49)			
Week 9 chg	76	-2.7 (2.35)	-2.71 (0.24)	118	-3.8 (2.56)	-3.71 (0.20)	-1.00 (-1.62, -0.38) [-0.40 (-0.69, -0.11)]	0.002
Week 10	76	4.1 (2.85)		118	3.1 (2.47)			
Week 10 chg	76	-2.7 (2.39)	-2.75 (0.24)	118	-3.8 (2.67)	-3.73 (0.20)	-0.99 (-1.61, -0.36) [-0.38 (-0.68, -0.09)]	0.002
Week 11	75	4.0 (2.78)		117	3.1 (2.44)			
Week 11 chg	75	-2.8 (2.37)	-2.81 (0.25)	117	-3.8 (2.60)	-3.81 (0.20)	-0.99 (-1.62, -0.37) [-0.40 (-0.69, -0.10)]	0.002
Week 12	76	4.0 (2.86)		118	3.0 (2.42)			
Week 12 chg	76	-2.8 (2.45)	-2.81 (0.24)	118	-3.9 (2.65)	-3.86 (0.20)	-1.04 (-1.67, -0.42) [-0.41 (-0.70, -0.12)]	0.001
Week 13	77	4.0 (2.93)		116	2.8 (2.47)			
Week 13 chg	77	-2.9 (2.38)	-2.90 (0.24)	116	-4.1 (2.68)	-4.03 (0.20)	-1.13 (-1.75, -0.51) [-0.44 (-0.73, -0.15)]	<.001
Week 14	76	3.9 (2.91)		113	2.8 (2.44)			

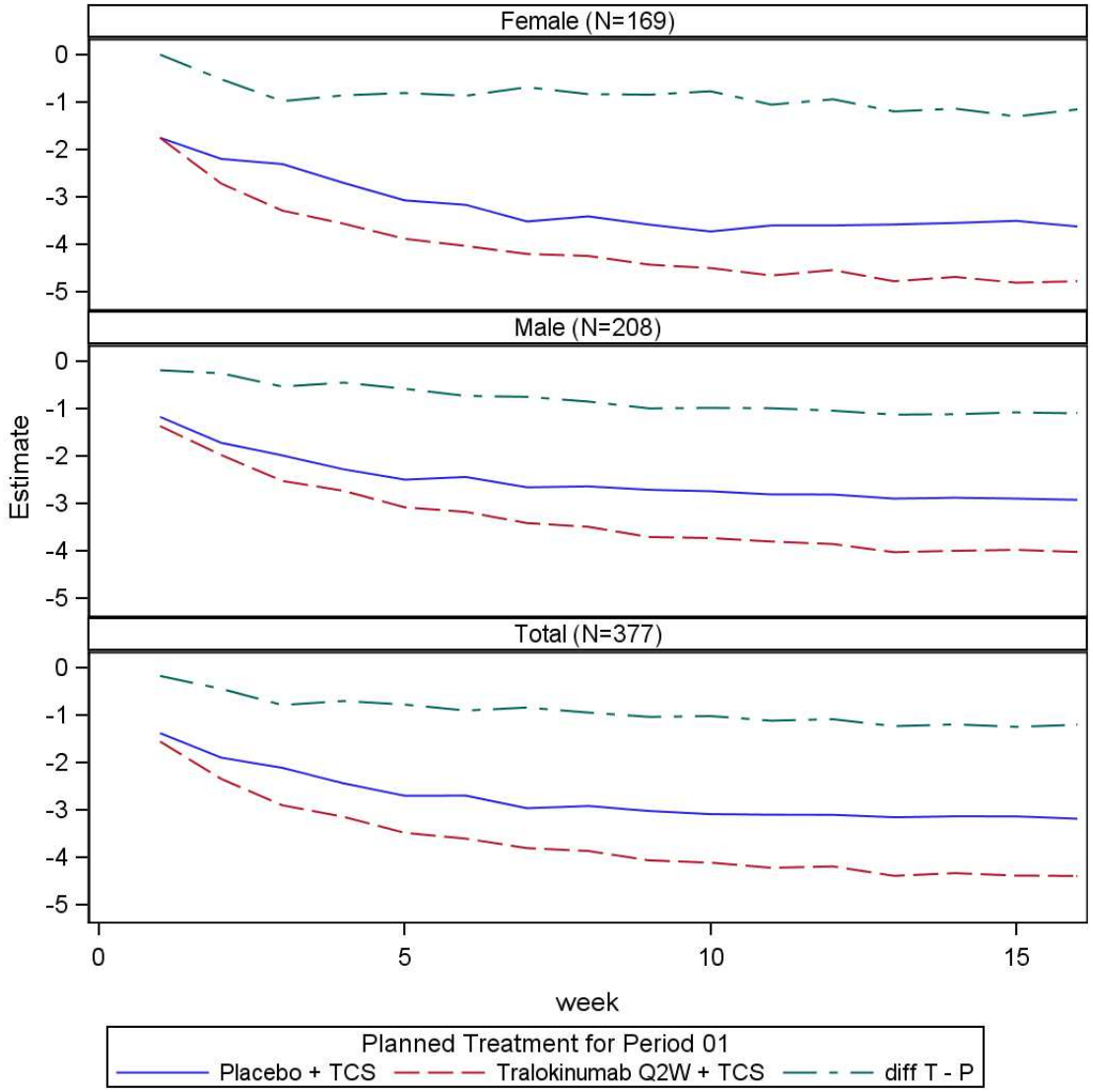
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3704
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.4.295.3.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	76	-2.9 (2.42)	-2.88 (0.24)	113	-4.1 (2.78)	-4.00 (0.20)	-1.12 (-1.74, -0.50) [-0.42 (-0.72, -0.13)]	<.001
Week 15	75	4.0 (2.95)		111	2.8 (2.42)			
Week 15 chg	75	-2.8 (2.38)	-2.90 (0.25)	111	-4.1 (2.67)	-3.98 (0.20)	-1.08 (-1.71, -0.46) [-0.42 (-0.72, -0.13)]	<.001
Week 16	73	3.8 (2.93)		114	2.7 (2.35)			
Week 16 chg	73	-2.9 (2.47)	-2.92 (0.25)	114	-4.1 (2.68)	-4.02 (0.20)	-1.10 (-1.72, -0.48) [-0.42 (-0.72, -0.13)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3704
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 1.4.295.3.2: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, 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 1.4.297.3.1: Total, Gender, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)		
Week 2		124 51.4 (17.14)			250 46.5 (16.69)		
Week 2 chg		124 -17.3 (16.94)	-16.83 (1.52)		250 -20.5 (14.91)	-20.64 (1.07)	-3.81 (-7.47, -0.15) 0.042 [-0.24 (-0.46, -0.03)]
Week 4		126 46.6 (20.16)			246 40.1 (16.71)		
Week 4 chg		126 -22.3 (19.12)	-21.68 (1.52)		246 -26.9 (15.62)	-26.91 (1.08)	-5.23 (-8.89, -1.57) 0.005 [-0.31 (-0.53, -0.09)]
Week 6		125 43.6 (20.47)			247 35.7 (16.22)		
Week 6 chg		125 -25.2 (18.79)	-24.72 (1.52)		247 -31.2 (15.78)	-31.15 (1.08)	-6.43 (-10.1, -2.76) <.001 [-0.38 (-0.60, -0.16)]
Week 8		122 41.9 (19.17)			243 32.7 (16.17)		
Week 8 chg		122 -26.8 (17.76)	-25.99 (1.53)		243 -34.2 (16.42)	-34.13 (1.08)	-8.15 (-11.8, -4.47) <.001 [-0.48 (-0.70, -0.26)]
Week 10		118 40.4 (20.53)			236 30.2 (16.85)		
Week 10 chg		118 -28.0 (19.22)	-27.39 (1.54)		236 -36.5 (18.20)	-36.38 (1.09)	-8.99 (-12.7, -5.29) <.001 [-0.48 (-0.71, -0.26)]
Week 12		119 39.6 (21.65)			238 29.4 (17.23)		
Week 12 chg		119 -28.8 (20.95)	-28.05 (1.53)		238 -37.6 (18.51)	-37.68 (1.08)	-9.63 (-13.3, -5.94) <.001 [-0.50 (-0.72, -0.27)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0024
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 1.4.297.3.1: Total, Gender, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	118	38.8 (22.39)		235	28.5 (18.20)		
Week 14 chg	118	-29.6 (21.97)	-28.76 (1.54)	235	-38.4 (18.95)	-38.28 (1.09)	-9.52 (-13.2, -5.82) <.001 [-0.48 (-0.70, -0.25)]
Week 16	122	40.9 (23.52)		241	29.4 (18.62)		
Week 16 chg	122	-27.7 (22.50)	-26.84 (1.53)	241	-37.4 (19.31)	-37.43 (1.08)	-10.59 (-14.3, -6.91) <.001 [-0.52 (-0.74, -0.30)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0024
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 1.4.297.3.1: Total, Gender, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	43	43 67.7 (11.29)		127	127 65.7 (12.82)			
Week 2		41 51.3 (17.68)			125 43.5 (15.85)			
Week 2 chg		41 -15.6 (17.34)	-14.64 (2.46)		125 -22.3 (14.88)	-22.45 (1.41)	-7.81 (-13.4, -2.20) [-0.50 (-0.86, -0.15)]	0.007
Week 4		43 44.6 (19.94)			123 37.0 (14.13)			
Week 4 chg		43 -23.1 (20.27)	-21.72 (2.44)		123 -28.7 (14.86)	-28.68 (1.41)	-6.96 (-12.6, -1.38) [-0.42 (-0.77, -0.07)]	0.015
Week 6		42 41.0 (22.08)			125 32.8 (14.05)			
Week 6 chg		42 -26.4 (20.37)	-25.37 (2.45)		125 -32.9 (15.84)	-32.90 (1.41)	-7.54 (-13.1, -1.93) [-0.44 (-0.79, -0.09)]	0.009
Week 8		41 39.8 (17.36)			122 29.9 (14.91)			
Week 8 chg		41 -27.1 (17.90)	-25.58 (2.46)		122 -35.7 (16.56)	-35.73 (1.42)	-10.15 (-15.8, -4.51) [-0.60 (-0.96, -0.24)]	<.001
Week 10		41 37.1 (18.52)			120 26.8 (14.60)			
Week 10 chg		41 -29.8 (19.50)	-28.22 (2.46)		120 -39.1 (17.17)	-39.02 (1.42)	-10.81 (-16.4, -5.17) [-0.61 (-0.97, -0.25)]	<.001
Week 12		39 34.2 (18.87)			120 26.2 (15.34)			
Week 12 chg		39 -32.3 (19.61)	-30.61 (2.49)		120 -39.5 (17.69)	-39.66 (1.42)	-9.05 (-14.7, -3.37) [-0.50 (-0.86, -0.13)]	0.002
Week 14		41 32.7 (19.98)			119 25.3 (16.62)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0024
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 1.4.297.3.1: Total, Gender, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	41	-34.2 (21.00)	-32.62 (2.46)	119	-40.4 (19.22)	-40.59 (1.42)	-7.97 (-13.6, -2.33) [-0.40 (-0.76, -0.05)]	0.006
Week 16	42	34.8 (21.24)		122	26.2 (16.58)			
Week 16 chg	42	-32.4 (22.68)	-30.41 (2.45)	122	-39.5 (18.79)	-39.59 (1.42)	-9.19 (-14.8, -3.58) [-0.46 (-0.82, -0.11)]	0.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0024
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 1.4.297.3.1: Total, Gender, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 69.5 (14.09)		125	125 68.2 (13.62)		
Week 2		83 51.4 (16.97)			125 49.5 (17.03)		
Week 2 chg		83 -18.1 (16.78)	-17.74 (1.93)		125 -18.7 (14.78)	-18.86 (1.57)	-1.12 (-6.02, 3.78) 0.653 [-0.07 (-0.35, 0.21)]
Week 4		83 47.6 (20.32)			123 43.2 (18.48)		
Week 4 chg		83 -21.8 (18.61)	-21.54 (1.93)		123 -25.1 (16.20)	-25.20 (1.58)	-3.67 (-8.57, 1.24) 0.143 [-0.21 (-0.49, 0.07)]
Week 6		83 44.9 (19.61)			122 38.7 (17.74)		
Week 6 chg		83 -24.5 (18.03)	-24.25 (1.93)		122 -29.5 (15.58)	-29.44 (1.58)	-5.19 (-10.1, -0.27) 0.039 [-0.31 (-0.59, -0.03)]
Week 8		81 42.9 (20.05)			121 35.4 (16.96)		
Week 8 chg		81 -26.7 (17.80)	-26.11 (1.94)		121 -32.7 (16.22)	-32.58 (1.58)	-6.47 (-11.4, -1.54) 0.010 [-0.38 (-0.67, -0.10)]
Week 10		77 42.1 (21.44)			116 33.8 (18.28)		
Week 10 chg		77 -27.1 (19.13)	-26.89 (1.95)		116 -33.8 (18.90)	-33.71 (1.59)	-6.82 (-11.8, -1.85) 0.007 [-0.36 (-0.65, -0.07)]
Week 12		80 42.2 (22.52)			118 32.6 (18.48)		
Week 12 chg		80 -27.0 (21.48)	-26.70 (1.94)		118 -35.6 (19.19)	-35.72 (1.59)	-9.02 (-14.0, -4.08) <.001 [-0.45 (-0.74, -0.16)]
Week 14		77 42.1 (23.04)			116 31.8 (19.20)		

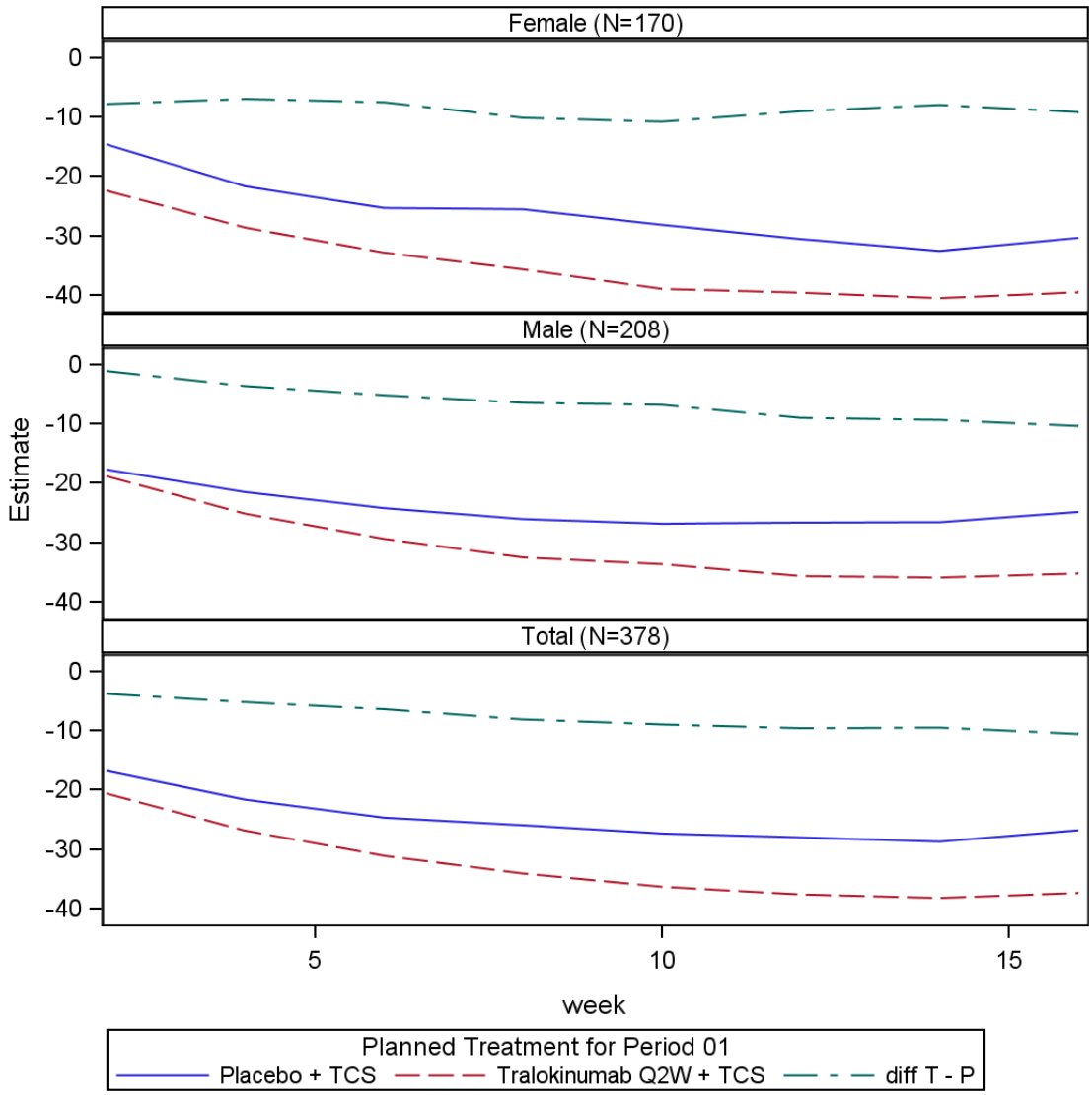
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0024
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.4.297.3.1: Total, Gender, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	77	-27.2 (22.22)	-26.63 (1.95)	116	-36.3 (18.53)	-35.99 (1.59)	-9.36 (-14.3, -4.39) [-0.47 (-0.76, -0.17)]	<.001
Week 16	80	44.1 (24.15)		119	32.7 (20.04)			
Week 16 chg	80	-25.2 (22.15)	-24.89 (1.94)	119	-35.3 (19.69)	-35.29 (1.59)	-10.39 (-15.3, -5.46) [-0.50 (-0.79, -0.21)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0024
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 1.4.297.3.2: Total, Gender, change in SCORAD, Treatment policy estimand, LP0162-1339, 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 1.4.299.3.1: Total, Gender, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score												
Total												
Baseline	126	125	17.2 (7.15)			252	250	17.6 (7.07)				
Week 2		121	9.8 (7.21)				249	8.6 (6.22)				
Week 2 chg		121	-7.3 (6.72)	-7.51 (0.53)			249	-9.0 (7.25)	-8.97 (0.37)		-1.46 (-2.73, -0.19)	0.024
											[-0.21 (-0.42, 0.01)]	
Week 4		122	9.1 (7.39)				245	7.4 (6.28)				
Week 4 chg		122	-8.1 (7.14)	-8.21 (0.53)			245	-10.2 (7.54)	-10.08 (0.37)		-1.87 (-3.14, -0.60)	0.004
											[-0.25 (-0.47, -0.03)]	
Week 6		123	8.4 (6.88)				242	6.3 (5.75)				
Week 6 chg		123	-8.8 (6.70)	-9.03 (0.53)			242	-11.3 (7.41)	-11.01 (0.37)		-1.99 (-3.25, -0.72)	0.002
											[-0.28 (-0.49, -0.06)]	
Week 8		120	8.1 (6.80)				239	6.2 (5.71)				
Week 8 chg		120	-9.1 (7.09)	-9.21 (0.53)			239	-11.6 (7.90)	-11.35 (0.37)		-2.14 (-3.41, -0.87)	0.001
											[-0.28 (-0.50, -0.06)]	
Week 12		116	7.9 (7.06)				227	5.7 (5.50)				
Week 12 chg		116	-9.0 (7.22)	-9.18 (0.53)			227	-11.9 (7.98)	-11.80 (0.38)		-2.62 (-3.90, -1.34)	<.001
											[-0.34 (-0.56, -0.11)]	
Week 16		119	8.4 (7.30)				237	5.7 (6.02)				
Week 16 chg		119	-8.8 (7.09)	-9.07 (0.53)			237	-11.8 (7.57)	-11.70 (0.38)		-2.64 (-3.91, -1.36)	<.001
											[-0.36 (-0.58, -0.13)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1553
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 1.4.299.3.1: Total, Gender, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	43	43 17.7 (7.17)		127	127 18.1 (6.86)		
Week 2		40 9.9 (6.88)			126 7.9 (6.02)		
Week 2 chg		40 -7.3 (6.46)	-7.60 (0.85)		126 -10.2 (7.15)	-10.04 (0.49)	-2.45 (-4.38, -0.51) 0.013 [-0.35 (-0.71, 0.01)]
Week 4		42 9.2 (7.39)			124 6.5 (5.78)		
Week 4 chg		42 -8.4 (6.64)	-8.81 (0.84)		124 -11.6 (7.39)	-11.35 (0.49)	-2.54 (-4.46, -0.62) 0.010 [-0.35 (-0.70, -0.00)]
Week 6		41 8.6 (7.13)			124 5.6 (4.97)		
Week 6 chg		41 -9.1 (6.43)	-9.49 (0.85)		124 -12.4 (7.28)	-12.24 (0.49)	-2.75 (-4.67, -0.82) 0.005 [-0.39 (-0.74, -0.03)]
Week 8		40 7.6 (6.16)			121 5.4 (4.66)		
Week 8 chg		40 -10.1 (7.46)	-10.31 (0.85)		121 -12.7 (7.72)	-12.49 (0.49)	-2.19 (-4.13, -0.25) 0.027 [-0.29 (-0.64, 0.07)]
Week 12		38 7.4 (6.31)			115 5.0 (4.98)		
Week 12 chg		38 -10.0 (7.27)	-10.06 (0.86)		115 -12.9 (7.84)	-12.94 (0.50)	-2.88 (-4.84, -0.92) 0.004 [-0.37 (-0.74, -0.00)]
Week 16		41 7.2 (6.54)			122 5.1 (5.47)		
Week 16 chg		41 -10.2 (6.97)	-10.61 (0.85)		122 -13.0 (7.43)	-12.77 (0.49)	-2.16 (-4.09, -0.23) 0.028 [-0.30 (-0.65, 0.06)]

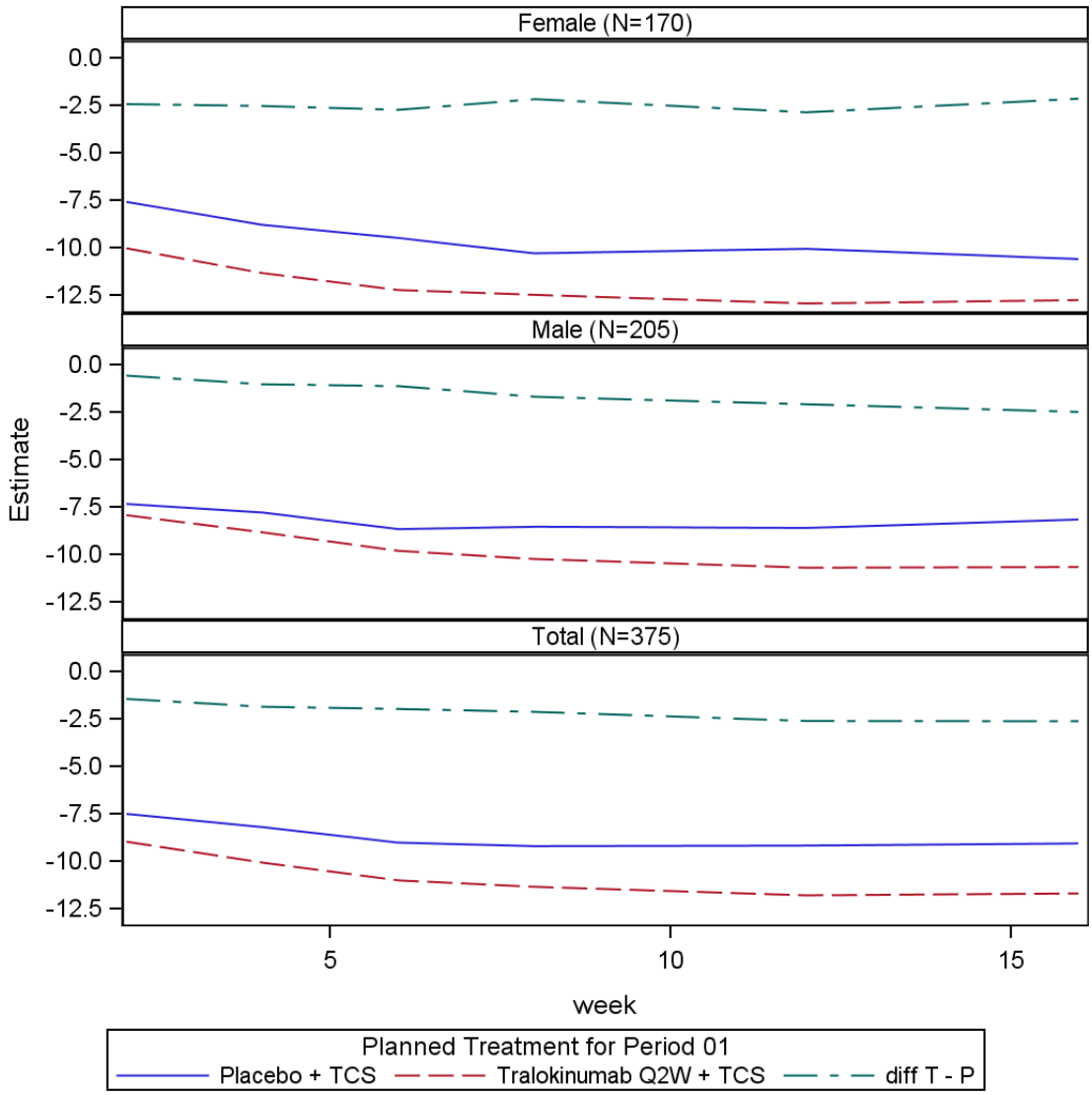
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.4.299.3.1: Total, Gender, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male										
Baseline	83	82	17.0 (7.18)		125	123	17.1 (7.27)			
Week 2		81	9.7 (7.40)			123	9.2 (6.39)			
Week 2 chg		81	-7.3 (6.88)	-7.35 (0.68)		123	-7.9 (7.20)	-7.93 (0.55)	-0.58 (-2.30, 1.14) [-0.08 (-0.36, 0.20)]	0.504
Week 4		80	9.1 (7.44)			121	8.3 (6.66)			
Week 4 chg		80	-7.9 (7.42)	-7.80 (0.68)		121	-8.9 (7.49)	-8.84 (0.55)	-1.04 (-2.77, 0.68) [-0.14 (-0.42, 0.14)]	0.235
Week 6		82	8.3 (6.79)			118	7.1 (6.40)			
Week 6 chg		82	-8.6 (6.86)	-8.67 (0.68)		118	-10.1 (7.38)	-9.82 (0.56)	-1.14 (-2.87, 0.58) [-0.16 (-0.44, 0.12)]	0.193
Week 8		80	8.4 (7.11)			118	6.9 (6.55)			
Week 8 chg		80	-8.6 (6.89)	-8.55 (0.68)		118	-10.5 (7.95)	-10.25 (0.56)	-1.70 (-3.43, 0.03) [-0.23 (-0.51, 0.06)]	0.054
Week 12		78	8.2 (7.42)			112	6.4 (5.93)			
Week 12 chg		78	-8.4 (7.18)	-8.61 (0.68)		112	-10.8 (8.03)	-10.71 (0.56)	-2.10 (-3.84, -0.36) [-0.27 (-0.56, 0.02)]	0.018
Week 16		78	9.0 (7.64)			115	6.4 (6.51)			
Week 16 chg		78	-8.0 (7.08)	-8.17 (0.68)		115	-10.7 (7.58)	-10.67 (0.56)	-2.50 (-4.24, -0.77) [-0.34 (-0.63, -0.05)]	0.005

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1553
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 1.4.299.3.2: Total, Gender, change in DLQI, Treatment policy estimand, LP0162-1339, 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 1.4.300.3.1: Total, Gender, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total											
Total											
Baseline	126	124	22.4 (5.63)			252	250	22.3 (5.09)			
Week 2		120	16.2 (7.55)				248	14.4 (6.85)			
Week 2 chg		120	-6.1 (6.67)	-6.14	(0.61)		248	-7.8 (6.57)	-7.88	(0.42)	-1.74 (-3.19, -0.29) 0.019 [-0.26 (-0.48, -0.04)]
Week 4		121	15.5 (7.82)				244	12.5 (6.95)			
Week 4 chg		121	-6.8 (7.00)	-6.89	(0.60)		244	-9.8 (7.02)	-9.82	(0.43)	-2.94 (-4.39, -1.48) <.001 [-0.42 (-0.64, -0.20)]
Week 6		122	14.7 (7.89)				242	11.4 (6.75)			
Week 6 chg		122	-7.7 (7.44)	-7.68	(0.60)		242	-10.9 (6.87)	-10.80	(0.43)	-3.12 (-4.57, -1.66) <.001 [-0.44 (-0.66, -0.22)]
Week 8		119	14.6 (7.88)				239	11.2 (7.08)			
Week 8 chg		119	-7.7 (7.38)	-7.60	(0.61)		239	-11.1 (7.24)	-11.05	(0.43)	-3.45 (-4.91, -1.99) <.001 [-0.47 (-0.70, -0.25)]
Week 12		115	14.0 (8.12)				227	10.6 (6.62)			
Week 12 chg		115	-8.2 (7.71)	-7.99	(0.61)		227	-11.6 (6.72)	-11.65	(0.43)	-3.67 (-5.14, -2.20) <.001 [-0.52 (-0.75, -0.29)]
Week 16		118	14.7 (8.27)				237	10.5 (7.20)			
Week 16 chg		118	-7.8 (7.40)	-7.85	(0.61)		237	-11.7 (7.37)	-11.68	(0.43)	-3.83 (-5.28, -2.37) <.001 [-0.52 (-0.74, -0.29)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0134
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 1.4.300.3.1: Total, Gender, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	43	42 21.5 (5.83)		127	127 22.3 (4.96)			
Week 2		39 15.3 (7.75)			125 13.8 (6.37)			
Week 2 chg		39 -5.9 (6.66)	-6.11 (1.00)		125 -8.4 (6.44)	-8.45 (0.56)	-2.35 (-4.61, -0.09) [-0.36 (-0.72, 0.00)]	0.042
Week 4		41 15.4 (7.75)			123 11.8 (6.42)			
Week 4 chg		41 -6.1 (6.50)	-6.37 (0.98)		123 -10.4 (6.74)	-10.37 (0.56)	-4.00 (-6.24, -1.76) [-0.60 (-0.96, -0.24)]	<.001
Week 6		40 13.9 (7.98)			124 10.9 (6.17)			
Week 6 chg		40 -7.6 (7.23)	-7.84 (0.99)		124 -11.3 (6.61)	-11.33 (0.56)	-3.49 (-5.74, -1.24) [-0.52 (-0.88, -0.15)]	0.003
Week 8		39 13.1 (7.44)			121 10.6 (6.44)			
Week 8 chg		39 -8.6 (6.84)	-8.62 (1.00)		121 -11.7 (7.08)	-11.65 (0.57)	-3.03 (-5.30, -0.77) [-0.43 (-0.80, -0.07)]	0.009
Week 12		37 11.7 (7.74)			115 10.0 (5.98)			
Week 12 chg		37 -9.4 (8.18)	-9.52 (1.01)		115 -12.3 (6.35)	-12.37 (0.57)	-2.85 (-5.14, -0.55) [-0.42 (-0.79, -0.04)]	0.015
Week 16		40 11.9 (7.29)			122 9.9 (6.72)			
Week 16 chg		40 -9.5 (7.03)	-9.88 (0.99)		122 -12.4 (7.27)	-12.36 (0.57)	-2.49 (-4.74, -0.23) [-0.34 (-0.70, 0.01)]	0.031

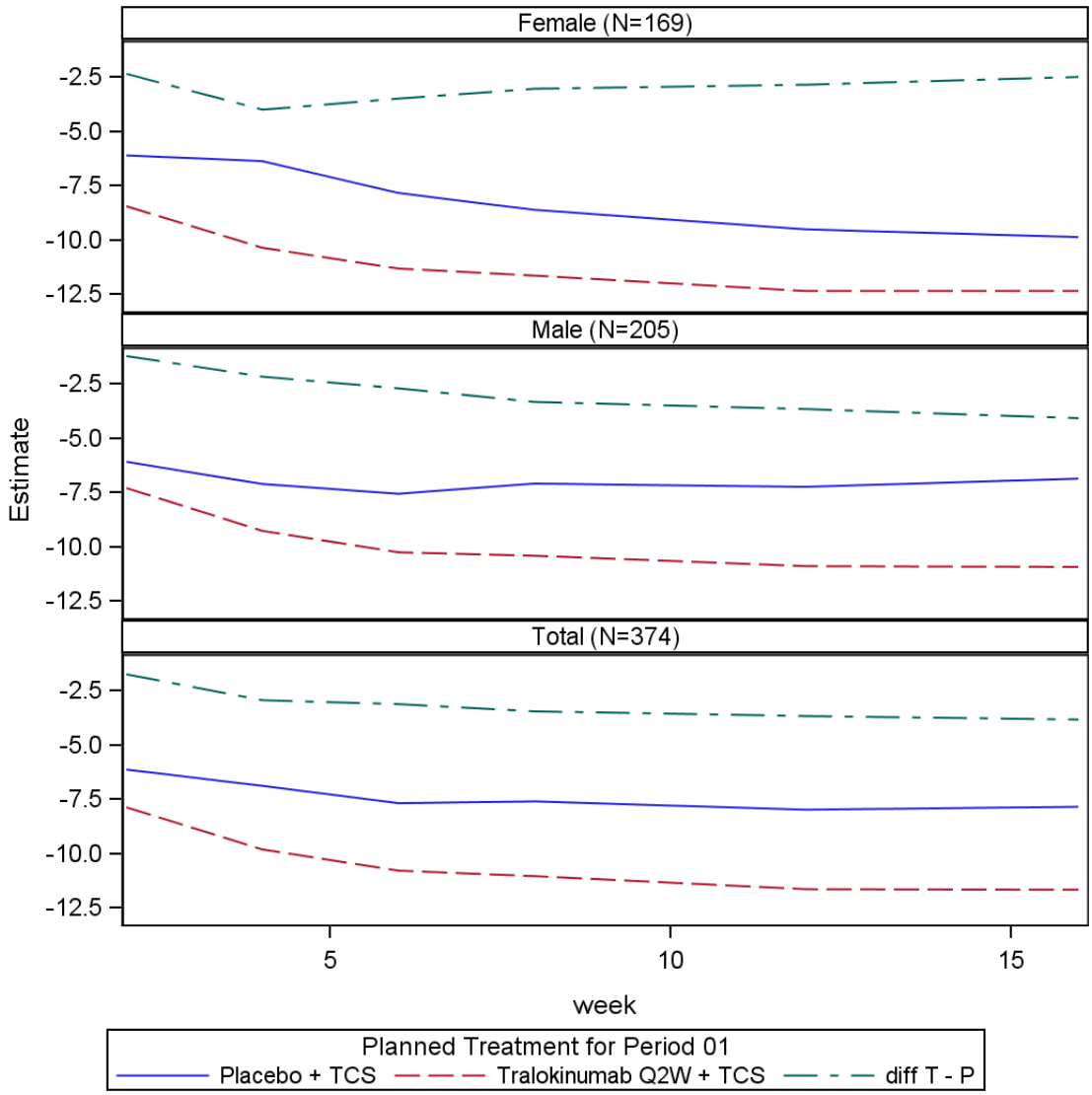
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0134
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.4.300.3.1: Total, Gender, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	82 22.8 (5.51)		125	123 22.3 (5.25)		
Week 2		81 16.6 (7.47)			123 15.1 (7.27)		
Week 2 chg		81 -6.2 (6.71)	-6.09 (0.77)		123 -7.2 (6.68)	-7.30 (0.63)	-1.21 (-3.17, 0.75) 0.226 [-0.18 (-0.46, 0.10)]
Week 4		80 15.5 (7.90)			121 13.1 (7.42)		
Week 4 chg		80 -7.2 (7.26)	-7.11 (0.77)		121 -9.2 (7.27)	-9.28 (0.63)	-2.16 (-4.13, -0.19) 0.031 [-0.30 (-0.58, -0.01)]
Week 6		82 15.0 (7.87)			118 11.9 (7.31)		
Week 6 chg		82 -7.7 (7.59)	-7.56 (0.77)		118 -10.4 (7.12)	-10.26 (0.63)	-2.70 (-4.67, -0.73) 0.007 [-0.37 (-0.65, -0.08)]
Week 8		80 15.4 (8.02)			118 11.8 (7.67)		
Week 8 chg		80 -7.2 (7.63)	-7.10 (0.77)		118 -10.5 (7.39)	-10.42 (0.63)	-3.33 (-5.30, -1.35) 0.001 [-0.44 (-0.73, -0.16)]
Week 12		78 15.1 (8.10)			112 11.1 (7.21)		
Week 12 chg		78 -7.6 (7.45)	-7.25 (0.78)		112 -10.9 (7.03)	-10.90 (0.64)	-3.66 (-5.64, -1.67) <.001 [-0.51 (-0.80, -0.21)]
Week 16		78 16.1 (8.42)			115 11.1 (7.66)		
Week 16 chg		78 -7.0 (7.48)	-6.87 (0.78)		115 -11.0 (7.44)	-10.94 (0.64)	-4.07 (-6.06, -2.09) <.001 [-0.55 (-0.84, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0134
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 1.4.300.3.2: Total, Gender, change in POEM, Treatment policy estimand, LP0162-1339, 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 1.4.318.3.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss								
Total								
Baseline	126	126 6.9 (2.72)		252	252 6.5 (2.77)			
Week 2		124 4.4 (3.05)			250 3.7 (2.95)			
Week 2 chg		124 -2.5 (2.93)	-2.39 (0.24)		250 -2.8 (2.95)	-2.85 (0.17)	-0.46 (-1.03, 0.11) [-0.16 (-0.37, 0.06)]	0.115
Week 4		126 3.7 (3.07)			246 3.1 (2.84)			
Week 4 chg		126 -3.1 (3.14)	-2.96 (0.24)		246 -3.3 (3.01)	-3.36 (0.17)	-0.40 (-0.97, 0.17) [-0.13 (-0.35, 0.08)]	0.167
Week 6		125 3.4 (2.99)			247 2.7 (2.75)			
Week 6 chg		125 -3.5 (3.05)	-3.31 (0.24)		247 -3.7 (3.04)	-3.71 (0.17)	-0.40 (-0.97, 0.17) [-0.13 (-0.35, 0.08)]	0.166
Week 8		122 3.4 (3.15)			243 2.5 (2.71)			
Week 8 chg		122 -3.4 (3.28)	-3.26 (0.24)		243 -3.9 (2.98)	-3.97 (0.17)	-0.71 (-1.28, -0.14) [-0.23 (-0.45, -0.01)]	0.015
Week 10		118 3.2 (2.97)			236 2.3 (2.60)			
Week 10 chg		118 -3.6 (3.11)	-3.48 (0.24)		236 -4.1 (3.15)	-4.17 (0.17)	-0.70 (-1.27, -0.12) [-0.22 (-0.44, -0.00)]	0.017
Week 12		119 3.1 (3.11)			238 2.2 (2.57)			
Week 12 chg		119 -3.7 (3.14)	-3.54 (0.24)		238 -4.2 (3.15)	-4.25 (0.17)	-0.71 (-1.29, -0.14) [-0.23 (-0.45, -0.01)]	0.015

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1666
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 VAS = Treatment*Week + [Baseline VAS]*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 1.4.318.3.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	3.0 (3.03)		235	2.0 (2.52)			
Week 14 chg	118	-3.8 (3.10)	-3.60 (0.24)	235	-4.4 (3.19)	-4.42 (0.17)	-0.82 (-1.39, -0.24) [-0.26 (-0.48, -0.04)]	0.005
Week 16	122	3.2 (3.24)		241	2.2 (2.68)			
Week 16 chg	122	-3.7 (3.20)	-3.46 (0.24)	241	-4.2 (3.34)	-4.27 (0.17)	-0.80 (-1.38, -0.23) [-0.24 (-0.46, -0.03)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1666
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 VAS = Treatment*Week + [Baseline VAS]*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 1.4.318.3.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	43	43 7.5 (2.16)		127	127 6.5 (2.78)		
Week 2		41 4.8 (3.05)			125 3.2 (2.88)		
Week 2 chg		41 -2.6 (3.14)	-2.32 (0.41)		125 -3.3 (3.11)	-3.37 (0.23)	-1.05 (-1.98, -0.12) 0.028 [-0.34 (-0.69, 0.02)]
Week 4		43 3.9 (3.26)			123 2.7 (2.73)		
Week 4 chg		43 -3.6 (3.33)	-3.10 (0.40)		123 -3.7 (3.10)	-3.80 (0.23)	-0.71 (-1.63, 0.22) 0.136 [-0.22 (-0.57, 0.12)]
Week 6		42 3.5 (3.10)			125 2.5 (2.57)		
Week 6 chg		42 -3.9 (3.19)	-3.57 (0.41)		125 -4.0 (2.93)	-4.05 (0.23)	-0.49 (-1.42, 0.44) 0.304 [-0.16 (-0.51, 0.19)]
Week 8		41 3.4 (2.99)			122 2.1 (2.50)		
Week 8 chg		41 -4.1 (3.31)	-3.55 (0.41)		122 -4.3 (2.98)	-4.49 (0.23)	-0.93 (-1.87, 0.00) 0.051 [-0.30 (-0.66, 0.05)]
Week 10		41 3.0 (3.01)			120 1.9 (2.55)		
Week 10 chg		41 -4.4 (3.14)	-3.91 (0.41)		120 -4.5 (3.04)	-4.63 (0.23)	-0.73 (-1.66, 0.21) 0.128 [-0.24 (-0.59, 0.12)]
Week 12		39 3.0 (3.04)			120 1.8 (2.29)		
Week 12 chg		39 -4.4 (3.17)	-3.84 (0.41)		120 -4.6 (3.03)	-4.83 (0.23)	-0.98 (-1.93, -0.04) 0.041 [-0.32 (-0.68, 0.04)]
Week 14		41 2.6 (2.82)			119 1.7 (2.48)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1666
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 VAS = Treatment*Week + [Baseline VAS]*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 1.4.318.3.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	41	-4.9 (3.18)	-4.25 (0.41)	119	-4.7 (3.31)	-4.90 (0.23)	-0.65 (-1.59, 0.29) [-0.20 (-0.55, 0.16)]	0.174
Week 16	42	3.0 (3.13)		122	1.8 (2.46)			
Week 16 chg	42	-4.5 (3.41)	-3.77 (0.41)	122	-4.6 (3.22)	-4.83 (0.23)	-1.06 (-1.99, -0.12) [-0.32 (-0.68, 0.03)]	0.026

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1666
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 VAS = Treatment*Week + [Baseline VAS]*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 1.4.318.3.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 6.6 (2.93)		125	125 6.4 (2.77)			
Week 2		83 4.1 (3.04)			125 4.1 (2.98)			
Week 2 chg		83 -2.4 (2.84)	-2.39 (0.29)		125 -2.3 (2.71)	-2.35 (0.24)	0.04 (-0.69, 0.78) [0.02 (-0.26, 0.29)]	0.909
Week 4		83 3.6 (2.99)			123 3.5 (2.91)			
Week 4 chg		83 -2.9 (3.03)	-2.86 (0.29)		123 -2.9 (2.88)	-2.93 (0.24)	-0.06 (-0.80, 0.68) [-0.02 (-0.30, 0.26)]	0.867
Week 6		83 3.3 (2.95)			122 3.0 (2.91)			
Week 6 chg		83 -3.2 (2.96)	-3.16 (0.29)		122 -3.4 (3.13)	-3.38 (0.24)	-0.21 (-0.95, 0.53) [-0.07 (-0.35, 0.21)]	0.572
Week 8		81 3.5 (3.25)			121 2.9 (2.86)			
Week 8 chg		81 -3.1 (3.23)	-3.07 (0.29)		121 -3.5 (2.95)	-3.46 (0.24)	-0.39 (-1.13, 0.35) [-0.13 (-0.41, 0.15)]	0.297
Week 10		77 3.3 (2.97)			116 2.6 (2.61)			
Week 10 chg		77 -3.2 (3.02)	-3.25 (0.29)		116 -3.8 (3.23)	-3.71 (0.24)	-0.46 (-1.21, 0.28) [-0.15 (-0.44, 0.14)]	0.223
Week 12		80 3.2 (3.16)			118 2.7 (2.76)			
Week 12 chg		80 -3.4 (3.09)	-3.36 (0.29)		118 -3.7 (3.22)	-3.70 (0.24)	-0.34 (-1.09, 0.40) [-0.11 (-0.39, 0.18)]	0.366
Week 14		77 3.2 (3.13)			116 2.3 (2.55)			

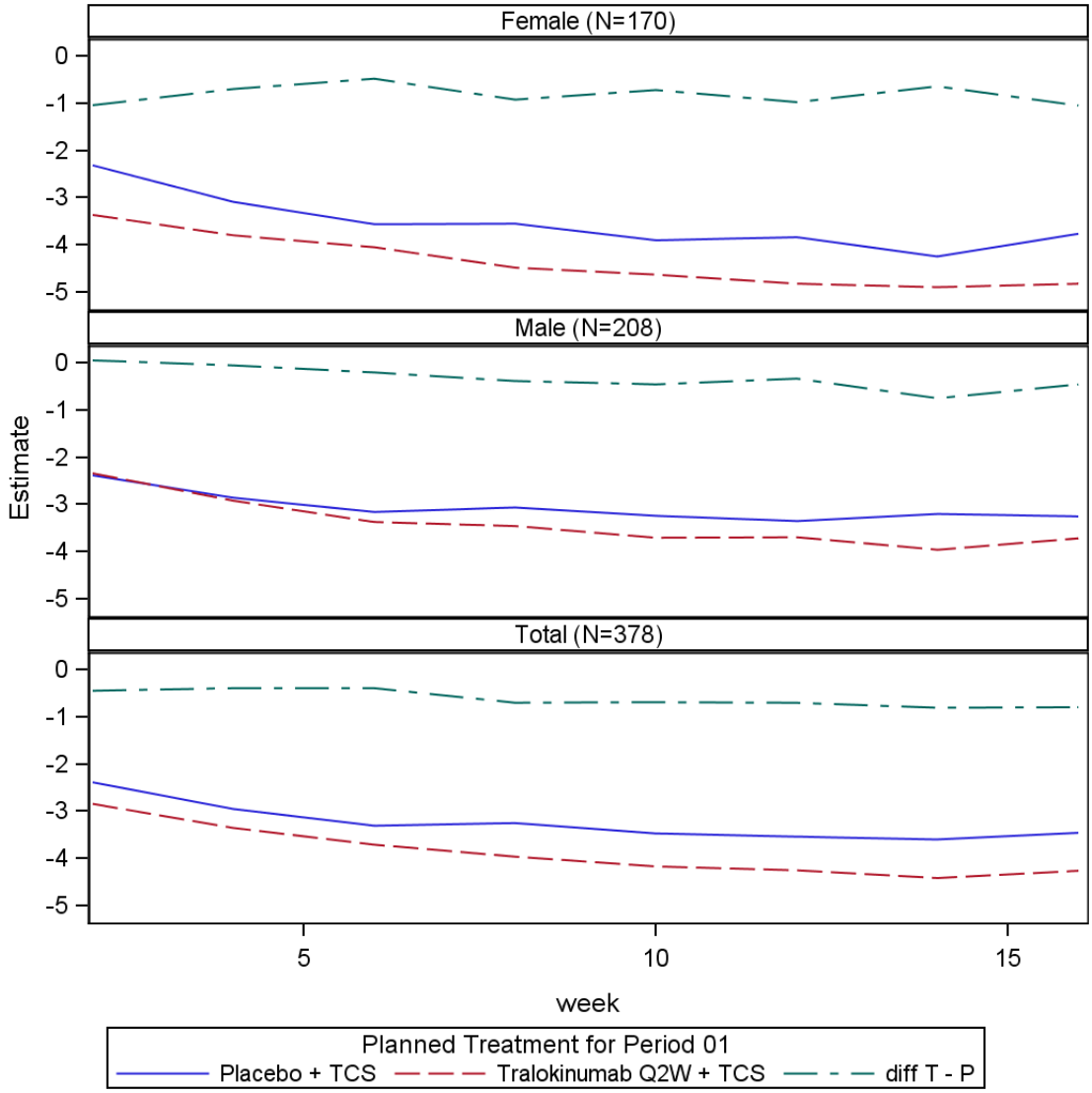
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1666
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*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 1.4.318.3.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	77	-3.2 (2.91)	-3.20 (0.29)	116	-4.1 (3.03)	-3.96 (0.24)	-0.76 (-1.51, -0.01) [-0.25 (-0.54, 0.03)]	0.047
Week 16	80	3.3 (3.31)		119	2.6 (2.84)			
Week 16 chg	80	-3.2 (3.02)	-3.26 (0.29)	119	-3.7 (3.41)	-3.72 (0.24)	-0.46 (-1.21, 0.28) [-0.14 (-0.43, 0.14)]	0.219

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1666
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 VAS = Treatment*Week + [Baseline VAS]*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 1.4.318.3.2: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 1.4.319.3.1: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	126	125	59.4 (23.09)		252	250	59.1 (25.01)		
Week 4		122	70.1 (18.94)			249	74.1 (18.34)		
Week 4 chg		122	10.3 (18.72)	11.01 (1.54)		249	15.0 (21.76)	15.00 (1.09)	3.99 (0.28, 7.69) 0.035 [0.19 (-0.03, 0.41)]
Week 8		120	71.2 (20.22)			237	75.5 (18.26)		
Week 8 chg		120	12.1 (23.42)	12.22 (1.55)		237	16.4 (23.73)	16.03 (1.10)	3.81 (0.07, 7.55) 0.046 [0.16 (-0.06, 0.38)]
Week 12		116	72.3 (21.36)			227	75.1 (18.28)		
Week 12 chg		116	12.1 (23.53)	12.65 (1.57)		227	16.4 (23.72)	15.70 (1.12)	3.04 (-0.74, 6.83) 0.115 [0.13 (-0.10, 0.35)]
Week 16		116	71.5 (21.22)			232	75.8 (18.84)		
Week 16 chg		116	12.4 (22.66)	12.51 (1.57)		232	17.0 (24.19)	16.27 (1.11)	3.77 (-0.01, 7.55) 0.051 [0.16 (-0.06, 0.38)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4848
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 VAS = Treatment*Week + [Baseline VAS]*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 1.4.319.3.1: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	43	43 61.4 (23.15)		127	127 60.2 (26.08)		
Week 4		42 70.4 (19.76)			126 75.6 (17.54)		
Week 4 chg		42 9.7 (16.32)	10.33 (2.62)		126 15.3 (23.66)	15.49 (1.51)	5.16 (-0.80, 11.12) 0.090 [0.23 (-0.12, 0.58)]
Week 8		40 70.1 (22.84)			120 77.2 (16.48)		
Week 8 chg		40 8.3 (26.96)	9.96 (2.67)		120 17.5 (25.23)	17.03 (1.54)	7.07 (0.98, 13.16) 0.023 [0.28 (-0.08, 0.63)]
Week 12		38 75.6 (22.98)			115 76.8 (16.37)		
Week 12 chg		38 11.1 (26.05)	13.96 (2.72)		115 18.1 (24.84)	16.99 (1.56)	3.03 (-3.17, 9.24) 0.337 [0.12 (-0.25, 0.49)]
Week 16		40 73.7 (22.62)			118 77.7 (16.81)		
Week 16 chg		40 11.9 (24.32)	13.42 (2.67)		118 18.8 (25.09)	17.55 (1.55)	4.14 (-1.96, 10.23) 0.183 [0.17 (-0.19, 0.53)]

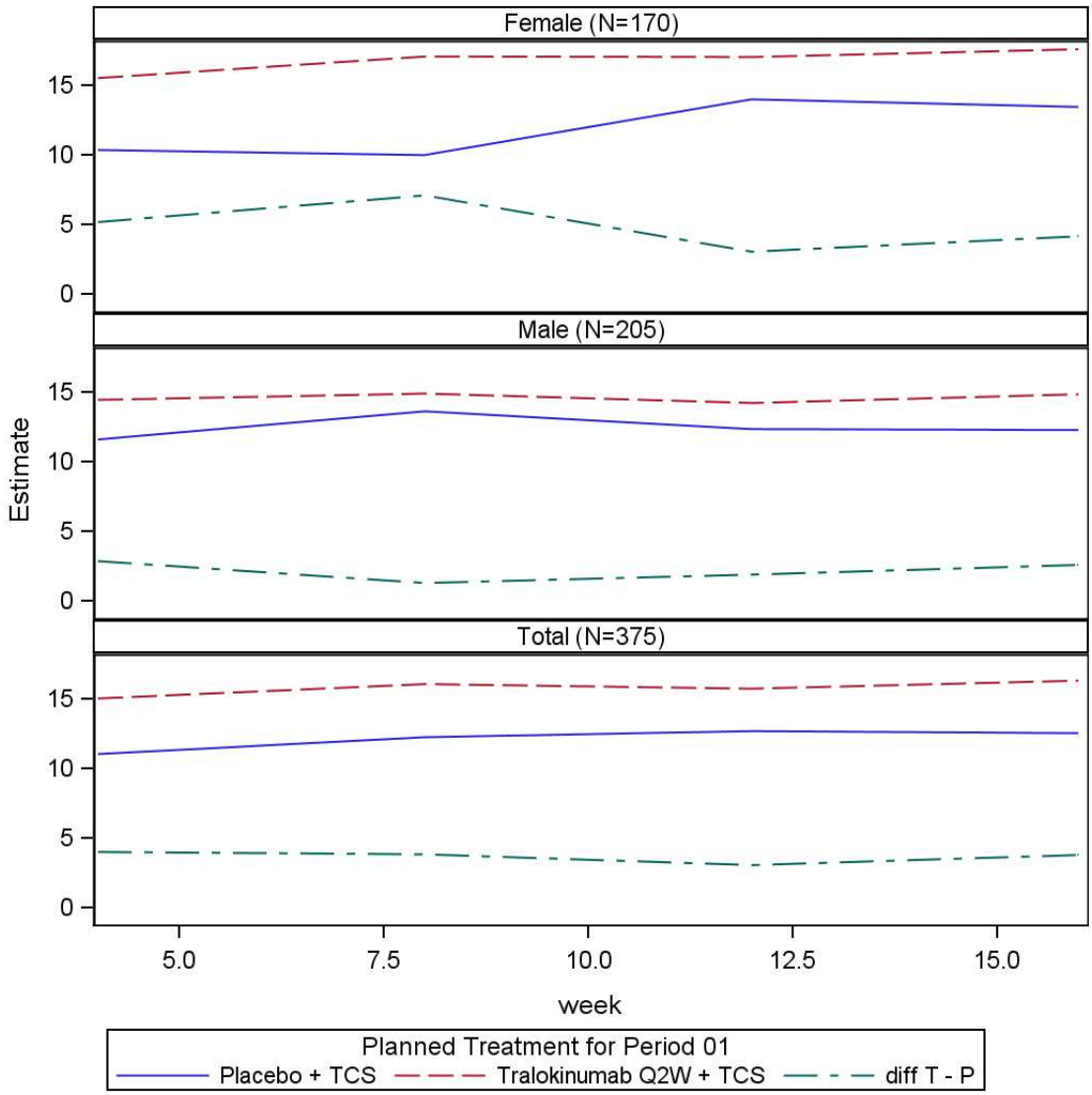
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4848
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*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 1.4.319.3.1: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	82 58.4 (23.13)		125	123 58.0 (23.90)		
Week 4		80 69.9 (18.63)			123 72.6 (19.09)		
Week 4 chg		80 10.6 (19.96)	11.57 (1.92)		123 14.6 (19.70)	14.41 (1.56)	2.84 (-2.03, 7.71) 0.253 [0.14 (-0.14, 0.43)]
Week 8		80 71.7 (18.91)			117 73.8 (19.84)		
Week 8 chg		80 14.0 (21.37)	13.59 (1.92)		117 15.3 (22.13)	14.86 (1.58)	1.27 (-3.63, 6.18) 0.611 [0.06 (-0.23, 0.34)]
Week 12		78 70.7 (20.50)			112 73.2 (19.97)		
Week 12 chg		78 12.6 (22.36)	12.31 (1.94)		112 14.7 (22.49)	14.18 (1.60)	1.87 (-3.07, 6.82) 0.457 [0.08 (-0.21, 0.37)]
Week 16		76 70.3 (20.51)			114 73.9 (20.62)		
Week 16 chg		76 12.6 (21.90)	12.24 (1.95)		114 15.2 (23.19)	14.81 (1.59)	2.57 (-2.39, 7.52) 0.310 [0.11 (-0.18, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4848
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 VAS = Treatment*Week + [Baseline VAS]*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 1.4.319.3.2: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 1.4.325.4.1: Total, Gender, EASI 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	88 (63.8)	15.3 (3.72;26.79)	1.3 (1.06; 1.62)	1.9 (1.16; 3.05)	0.0104	0.6818
Placebo + TCS	137	67 (48.9)					
Female							
Tralokinumab Q2W + TCS	57	40 (70.2)	12.1 (-5.49;29.63)	1.2 (0.91; 1.60)	1.7 (0.77; 3.80)	0.1819	
Placebo + TCS	54	32 (59.3)					
Male							
Tralokinumab Q2W + TCS	81	48 (59.3)	17.6 (2.30;32.89)	1.4 (1.04; 1.94)	2.0 (1.08; 3.69)	0.0248	
Placebo + TCS	83	35 (42.2)					

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 Prior CSA use and baseline IGA.

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Table 1.4.326.4.1: Total, Gender, EASI 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	57 (41.3)	14.2 (3.21;25.12)	1.5 (1.09; 2.10)	1.9 (1.15; 3.21)	0.0123	0.5304
Placebo + TCS	137	38 (27.7)					
Female							
Tralokinumab Q2W + TCS	57	27 (47.4)	11.1 (-7.04;29.18)	1.3 (0.83; 2.04)	1.6 (0.74; 3.44)	0.2340	
Placebo + TCS	54	20 (37.0)					
Male							
Tralokinumab Q2W + TCS	81	30 (37.0)	16.1 (2.47;29.75)	1.7 (1.07; 2.86)	2.2 (1.11; 4.50)	0.0228	
Placebo + TCS	83	18 (21.7)					

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 Prior CSA use and baseline IGA.

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Table 1.4.329.4.1: Total, Gender, SCORAD 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	40 (29.0)	16.9 (7.55;26.16)	2.4 (1.42; 3.96)	3.0 (1.58; 5.62)	0.0006	0.3981
Placebo + TCS	137	17 (12.4)					
Female							
Tralokinumab Q2W + TCS	57	19 (33.3)	15.5 (-0.50;31.51)	1.9 (0.94; 3.65)	2.3 (0.94; 5.56)	0.0661	
Placebo + TCS	54	10 (18.5)					
Male							
Tralokinumab Q2W + TCS	81	21 (25.9)	17.8 (6.53;29.11)	3.2 (1.41; 7.22)	3.9 (1.53; 9.84)	0.0026	
Placebo + TCS	83	7 (8.4)					

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 Prior CSA use and baseline IGA.

Table 1.4.330.4.1: Total, Gender, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	134	62 (46.3)	9.7 (-1.99;21.41)	1.3 (0.95; 1.69)	1.5 (0.92; 2.44)	0.1068	0.5380
Placebo + TCS	135	49 (36.3)					
Female							
Tralokinumab Q2W + TCS	57	29 (50.9)	6.2 (-12.4;24.79)	1.1 (0.77; 1.69)	1.3 (0.60; 2.73)	0.5223	
Placebo + TCS	53	24 (45.3)					
Male							
Tralokinumab Q2W + TCS	77	33 (42.9)	12.4 (-2.64;27.39)	1.4 (0.92; 2.17)	1.7 (0.89; 3.25)	0.1093	
Placebo + TCS	82	25 (30.5)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

Table 1.4.331.4.1: Total, Gender, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	137	85 (62.0)	11.3 (-0.46;23.02)	1.2 (0.99; 1.51)	1.6 (0.98; 2.55)	0.0614	0.1076
Placebo + TCS	136	69 (50.7)					
Female							
Tralokinumab Q2W + TCS	57	35 (61.4)	-0.5 (-18.6;17.67)	1.0 (0.74; 1.34)	1.0 (0.45; 2.13)	0.9582	
Placebo + TCS	53	33 (62.3)					
Male							
Tralokinumab Q2W + TCS	80	50 (62.5)	19.6 (4.23;34.99)	1.5 (1.07; 2.00)	2.1 (1.16; 3.97)	0.0132	
Placebo + TCS	83	36 (43.4)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 3.

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Table 1.4.333.4.1: Total, Gender, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	135	105 (77.8)	18.9 (8.08;29.81)	1.3 (1.12; 1.56)	2.5 (1.44; 4.20)	0.0009	0.7831
Placebo + TCS	134	79 (59.0)					
Female							
Tralokinumab Q2W + TCS	55	41 (74.5)	18.2 (0.38;36.06)	1.3 (0.99; 1.77)	2.2 (1.00; 5.07)	0.0516	
Placebo + TCS	53	30 (56.6)					
Male							
Tralokinumab Q2W + TCS	80	64 (80.0)	19.3 (5.40;33.14)	1.3 (1.07; 1.63)	2.6 (1.27; 5.20)	0.0080	
Placebo + TCS	81	49 (60.5)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

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Table 1.4.335.4.1: Total, Gender, DLQI 0/1, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	32 (23.2)	6.9 (-2.56;16.32)	1.4 (0.87; 2.35)	1.5 (0.85; 2.81)	0.1545	0.0217
Placebo + TCS	136	22 (16.2)					
Female							
Tralokinumab Q2W + TCS	57	13 (22.8)	-4.7 (-21.0;11.60)	0.8 (0.42; 1.61)	0.8 (0.33; 1.84)	0.5730	
Placebo + TCS	54	15 (27.8)					
Male							
Tralokinumab Q2W + TCS	81	19 (23.5)	15.1 (4.03;26.10)	2.8 (1.23; 6.44)	3.3 (1.31; 8.50)	0.0093	
Placebo + TCS	82	7 (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. #: 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 Prior CSA use and baseline IGA.

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Table 1.4.355.4.1: Total, Gender, EASI 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	96 (69.6)	16.8 (5.65;27.89)	1.3 (1.09; 1.59)	2.1 (1.27; 3.49)	0.0039	0.3589
Placebo + TCS	137	73 (53.3)					
Female							
Tralokinumab Q2W + TCS	57	40 (70.2)	8.8 (-8.67;26.22)	1.1 (0.87; 1.50)	1.5 (0.67; 3.33)	0.3296	
Placebo + TCS	54	33 (61.1)					
Male							
Tralokinumab Q2W + TCS	81	56 (69.1)	22.1 (7.58;36.58)	1.5 (1.12; 1.92)	2.6 (1.35; 4.97)	0.0039	
Placebo + TCS	83	40 (48.2)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.4.356.4.1: Total, Gender, EASI 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	67 (48.6)	14.1 (2.87;25.40)	1.4 (1.06; 1.86)	1.8 (1.12; 3.04)	0.0160	0.3285
Placebo + TCS	137	48 (35.0)					
Female							
Tralokinumab Q2W + TCS	57	27 (47.4)	6.8 (-11.9;25.51)	1.2 (0.75; 1.81)	1.3 (0.62; 2.76)	0.4714	
Placebo + TCS	54	22 (40.7)					
Male							
Tralokinumab Q2W + TCS	81	40 (49.4)	19.2 (4.62;33.78)	1.6 (1.10; 2.42)	2.3 (1.19; 4.38)	0.0113	
Placebo + TCS	83	26 (31.3)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.4.359.4.1: Total, Gender, SCORAD 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	53 (38.4)	20.6 (10.39;30.82)	2.1 (1.42; 3.22)	3.0 (1.68; 5.21)	0.0001	0.2404
Placebo + TCS	137	25 (18.2)					
Female							
Tralokinumab Q2W + TCS	57	20 (35.1)	13.8 (-2.95;30.64)	1.7 (0.87; 3.18)	2.0 (0.85; 4.53)	0.1046	
Placebo + TCS	54	12 (22.2)					
Male							
Tralokinumab Q2W + TCS	81	33 (40.7)	25.6 (12.50;38.76)	2.7 (1.52; 4.77)	3.9 (1.83; 8.38)	0.0003	
Placebo + TCS	83	13 (15.7)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.4.360.4.1: Total, Gender, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	134	64 (47.8)	8.3 (-3.43;20.09)	1.2 (0.92; 1.60)	1.4 (0.87; 2.29)	0.1650	0.9211
Placebo + TCS	135	53 (39.3)					
Female							
Tralokinumab Q2W + TCS	57	31 (54.4)	8.2 (-10.9;27.29)	1.2 (0.79; 1.76)	1.4 (0.66; 2.87)	0.3949	
Placebo + TCS	53	24 (45.3)					
Male							
Tralokinumab Q2W + TCS	77	33 (42.9)	7.6 (-7.57;22.79)	1.2 (0.81; 1.83)	1.4 (0.73; 2.62)	0.3242	
Placebo + TCS	82	29 (35.4)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.4.361.4.1: Total, Gender, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	137	86 (62.8)	16.0 (4.45;27.60)	1.3 (1.08; 1.67)	1.9 (1.19; 3.16)	0.0078	0.3444
Placebo + TCS	136	64 (47.1)					
Female							
Tralokinumab Q2W + TCS	57	36 (63.2)	9.0 (-9.46;27.47)	1.2 (0.84; 1.61)	1.4 (0.68; 3.10)	0.3415	
Placebo + TCS	53	29 (54.7)					
Male							
Tralokinumab Q2W + TCS	80	50 (62.5)	21.4 (6.64;36.24)	1.5 (1.12; 2.06)	2.4 (1.29; 4.64)	0.0061	
Placebo + TCS	83	35 (42.2)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.4.363.4.1: Total, Gender, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	135	105 (77.8)	21.3 (10.39;32.18)	1.4 (1.16; 1.64)	2.7 (1.59; 4.63)	0.0002	0.5795
Placebo + TCS	134	76 (56.7)					
Female							
Tralokinumab Q2W + TCS	55	41 (74.5)	17.4 (-0.50;35.28)	1.3 (0.98; 1.75)	2.2 (0.96; 4.90)	0.0603	
Placebo + TCS	53	30 (56.6)					
Male							
Tralokinumab Q2W + TCS	80	64 (80.0)	23.5 (9.56;37.54)	1.4 (1.13; 1.77)	3.0 (1.51; 6.13)	0.0015	
Placebo + TCS	81	46 (56.8)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.4.365.4.1: Total, Gender, DLQI 0/1, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	36 (26.1)	13.7 (4.62;22.81)	2.1 (1.25; 3.56)	2.5 (1.34; 4.85)	0.0038	0.1836
Placebo + TCS	136	17 (12.5)					
Female							
Tralokinumab Q2W + TCS	57	15 (26.3)	7.2 (-8.11;22.46)	1.4 (0.68; 2.82)	1.5 (0.61; 3.84)	0.3687	
Placebo + TCS	54	10 (18.5)					
Male							
Tralokinumab Q2W + TCS	81	21 (25.9)	18.0 (6.81;29.13)	3.2 (1.42; 7.03)	4.1 (1.59;10.49)	0.0024	
Placebo + TCS	82	7 (8.5)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.4.385.4.1: Total, Gender, SCORAD 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	13 (9.4)	4.5 (-1.61;10.59)	1.9 (0.78; 4.54)	2.0 (0.77; 5.17)	0.1522	0.9445
Placebo + TCS	137	7 (5.1)					
Female							
Tralokinumab Q2W + TCS	57	6 (10.5)	5.6 (-4.40;15.50)	2.1 (0.53; 8.00)	2.2 (0.51; 9.67)	0.2882	
Placebo + TCS	54	3 (5.6)					
Male							
Tralokinumab Q2W + TCS	81	7 (8.6)	4.1 (-3.47;11.76)	1.9 (0.56; 6.49)	2.0 (0.55; 7.24)	0.2921	
Placebo + TCS	83	4 (4.8)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

Table 1.4.389.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)											
Total											
Baseline	137	136	7.5 (1.37)			138	137	7.3 (1.45)			
Week 16		123	4.2 (2.30)				124	3.3 (2.05)			
Week 16 chg		122	-3.3 (2.36)	-3.21	(0.19)		123	-3.9 (2.06)	-3.98	(0.19)	-0.77 (-1.30, -0.24) 0.004 [-0.35 (-0.60, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0647
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.389.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	54	53 7.7 (1.40)		57	57 7.6 (1.42)			
Week 16		51 3.7 (2.42)			52 3.4 (2.39)			
Week 16 chg		50 -3.9 (2.55)	-3.84 (0.33)		52 -4.2 (2.45)	-4.22 (0.33)	-0.38 (-1.31, 0.55) [-0.15 (-0.54, 0.24)]	0.416

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0647
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.389.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 7.3 (1.34)		81	80 7.0 (1.43)			
Week 16		72 4.6 (2.16)			72 3.3 (1.77)			
Week 16 chg		72 -2.8 (2.13)	-2.75 (0.22)		71 -3.7 (1.71)	-3.82 (0.22)	-1.07 (-1.69, -0.45) [-0.56 (-0.89, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0647
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.390.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 16		123 3.2 (2.41)			124 2.4 (2.16)		
Week 16 chg		122 -3.7 (2.29)	-3.50 (0.19)		123 -3.9 (2.32)	-4.03 (0.19)	-0.53 (-1.07, 0.01) 0.052 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0191
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.390.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 6.9 (1.84)		57	57 6.7 (2.11)		
Week 16		51 2.6 (2.46)			52 2.5 (2.42)		
Week 16 chg		50 -4.3 (2.28)	-4.18 (0.32)		52 -4.2 (2.68)	-4.23 (0.31)	-0.04 (-0.93, 0.85) 0.922 [-0.02 (-0.41, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0191
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.390.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 6.9 (1.52)		81	80 6.1 (2.08)			
Week 16		72 3.7 (2.27)			72 2.4 (1.98)			
Week 16 chg		72 -3.2 (2.22)	-2.99 (0.23)		71 -3.7 (2.00)	-3.91 (0.23)	-0.93 (-1.59, -0.26) [-0.44 (-0.77, -0.11)]	0.007

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0191
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.391.4.1: Total, Gender, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 16		124 36.3 (18.78)			123 27.0 (16.90)		
Week 16 chg		124 -34.7 (19.94)	-34.36 (1.54)		123 -43.3 (19.46)	-43.61 (1.55)	-9.25 (-13.6, -4.94) <.001 [-0.47 (-0.72, -0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0258
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.391.4.1: Total, Gender, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 72.0 (13.89)		57	57 71.2 (11.89)		
Week 16		48 31.9 (20.57)			50 25.7 (16.80)		
Week 16 chg		48 -39.9 (21.41)	-39.91 (2.61)		50 -46.3 (20.53)	-46.26 (2.55)	-6.34 (-13.6, 0.90) 0.085 [-0.30 (-0.70, 0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0258
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.391.4.1: Total, Gender, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 70.0 (12.13)		81	81 69.5 (12.18)			
Week 16		76 39.1 (17.10)			73 27.9 (17.02)			
Week 16 chg		76 -31.4 (18.33)	-30.81 (1.88)		73 -41.2 (18.55)	-41.87 (1.93)	-11.06 (-16.4, -5.72) [-0.60 (-0.93, -0.27)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0258
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.392.4.1: Total, Gender, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 16		122 6.4 (5.60)			119 4.5 (3.87)		
Week 16 chg		120 -10.0 (6.54)	-9.61 (0.40)		118 -11.0 (5.99)	-11.29 (0.41)	-1.68 (-2.82, -0.55) 0.004 [-0.27 (-0.52, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2592
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.392.4.1: Total, Gender, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 17.2 (6.62)		57	57 17.1 (6.83)		
Week 16		46 5.9 (6.46)			47 4.6 (4.28)		
Week 16 chg		45 -11.4 (6.88)	-11.15 (0.75)		47 -12.3 (6.39)	-12.42 (0.73)	-1.27 (-3.35, 0.81) 0.227 [-0.19 (-0.60, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2592
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.392.4.1: Total, Gender, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	81 15.8 (6.11)		81	80 15.0 (6.22)			
Week 16		76 6.7 (5.03)			72 4.4 (3.60)			
Week 16 chg		75 -9.1 (6.23)	-8.64 (0.47)		71 -10.1 (5.60)	-10.59 (0.48)	-1.95 (-3.28, -0.62) [-0.33 (-0.66, -0.00)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2592
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.393.4.1: Total, Gender, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 16		122 12.9 (7.67)			119 9.0 (5.53)			
Week 16 chg		120 -8.0 (8.09)	-8.10 (0.59)		116 -12.2 (6.39)	-12.12 (0.60)	-4.02 (-5.68, -2.36) [-0.55 (-0.81, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5413
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.393.4.1: Total, Gender, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	54	53 21.2 (5.64)		57	55 21.7 (5.28)			
Week 16		46 12.5 (7.79)			47 8.7 (5.21)			
Week 16 chg		45 -8.9 (8.77)	-9.10 (1.00)		45 -13.2 (6.73)	-13.04 (0.99)	-3.94 (-6.74, -1.14) [-0.50 (-0.92, -0.08)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5413
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.393.4.1: Total, Gender, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	81 20.6 (5.80)		81	80 21.0 (5.02)		
Week 16		76 13.1 (7.63)			72 9.2 (5.76)		
Week 16 chg		75 -7.5 (7.67)	-7.51 (0.74)		71 -11.5 (6.12)	-11.54 (0.76)	-4.02 (-6.11, -1.94) <.001 [-0.58 (-0.91, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5413
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.395.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score											
Total											
Baseline	137	134	52.5 (21.97)			138	135	56.6 (19.90)			
Week 16		122	69.3 (21.69)				119	75.7 (16.92)			
Week 16 chg		120	16.7 (26.74)	14.64	(1.75)		116	17.7 (22.49)	19.84	(1.78)	5.21 (0.28, 10.14) 0.039 [0.21 (-0.05, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4059
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.395.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female											
Baseline	54	53	48.5 (21.94)			57	55	56.9 (21.30)			
Week 16		46	70.3 (24.33)				47	73.5 (19.42)			
Week 16 chg		45	21.4 (30.03)	18.13	(3.31)		45	16.2 (25.51)	19.34	(3.31)	1.22 (-8.17, 10.61) 0.797 [0.04 (-0.37, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4059
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.395.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	81 55.1 (21.74)		81	80 56.4 (19.01)			
Week 16		76 68.6 (20.07)			72 77.2 (15.05)			
Week 16 chg		75 13.9 (24.34)	12.43 (1.99)		71 18.6 (20.48)	20.23 (2.05)	7.80 (2.14, 13.45) [0.35 (0.02, 0.67)]	0.007

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4059
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.396.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss									
Total									
Baseline	137	137	6.7 (2.21)		138	138	6.7 (2.36)		
Week 16		124	2.7 (2.77)			123	1.9 (2.39)		
Week 16 chg		124	-4.1 (3.25)	-3.99 (0.23)		123	-4.7 (2.92)	-4.72 (0.23)	-0.73 (-1.36, -0.09) 0.025 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0029
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.396.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	54	54 7.3 (1.97)		57	57 7.1 (2.25)			
Week 16		48 1.9 (2.50)			50 2.1 (2.82)			
Week 16 chg		48 -5.5 (2.86)	-5.32 (0.38)		50 -4.9 (3.30)	-5.05 (0.37)	0.27 (-0.80, 1.33) [0.09 (-0.31, 0.48)]	0.621

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0029
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.396.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 6.4 (2.28)		81	81 6.4 (2.41)			
Week 16		76 3.2 (2.82)			73 1.8 (2.07)			
Week 16 chg		76 -3.2 (3.20)	-3.14 (0.27)		73 -4.5 (2.64)	-4.51 (0.28)	-1.37 (-2.15, -0.59) [-0.47 (-0.79, -0.14)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0029
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.398.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score											
Total											
Baseline	137	134	52.5 (21.97)			138	135	56.6 (19.90)			
Week 26		115	72.6 (20.73)				119	76.4 (17.30)			
Week 26 chg		113	20.5 (25.83)	18.74	(1.72)		116	19.5 (21.18)	21.31	(1.70)	2.56 (-2.22, 7.35) 0.292 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0382
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.398.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female											
Baseline	54	53	48.5 (21.94)			57	55	56.9 (21.30)			
Week 26		44	76.5 (22.80)				51	75.4 (20.87)			
Week 26 chg		43	29.4 (27.39)	25.33	(3.30)		49	18.5 (25.21)	22.07	(3.08)	-3.25 (-12.4, 5.86) 0.480 [-0.12 (-0.53, 0.29)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0382
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.398.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male											
Baseline	83	81	55.1 (21.74)			81	80	56.4 (19.01)			
Week 26		71	70.2 (19.10)				68	77.2 (14.16)			
Week 26 chg		70	15.1 (23.38)	14.56	(1.86)		67	20.3 (17.83)	21.08	(1.90)	6.52 (1.25, 11.79) 0.016 [0.31 (-0.02, 0.65)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0382
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.401.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.56 (0.82)		138 -12.9 (10.72)	-13.28 (0.82)	-0.72 (-3.02, 1.57) 0.536 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.48 (0.83)		137 -18.8 (10.58)	-19.37 (0.82)	-1.88 (-4.18, 0.42) 0.109 [-0.17 (-0.41, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.42 (0.83)		134 -20.9 (11.93)	-21.43 (0.83)	-3.01 (-5.32, -0.70) 0.011 [-0.25 (-0.49, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.19 (0.83)		130 -22.5 (12.16)	-23.11 (0.83)	-3.92 (-6.23, -1.60) <.001 [-0.30 (-0.54, -0.06)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.50 (0.83)		130 -24.3 (11.55)	-24.96 (0.83)	-4.46 (-6.78, -2.14) <.001 [-0.35 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-20.99 (0.84)		128 -24.7 (12.40)	-25.11 (0.84)	-4.13 (-6.46, -1.80) <.001 [-0.31 (-0.56, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3823
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.401.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 11.2 (11.57)			127 7.0 (8.34)		
Week 14 chg		126 -22.8 (14.69)	-21.74 (0.84)		127 -25.1 (13.29)	-25.62 (0.84)	-3.87 (-6.21, -1.54) 0.001 [-0.28 (-0.52, -0.03)]
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.54 (0.84)		123 -25.9 (12.78)	-26.06 (0.84)	-3.52 (-5.86, -1.17) 0.003 [-0.25 (-0.50, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3823
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.401.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 33.2 (14.65)		57	57 33.2 (12.33)		
Week 2		54 19.4 (14.30)			57 18.9 (13.09)		
Week 2 chg		54 -13.8 (10.42)	-13.81 (1.28)		57 -14.3 (11.11)	-14.37 (1.24)	-0.56 (-4.07, 2.95) 0.754 [-0.05 (-0.42, 0.32)]
Week 4		53 14.0 (12.45)			57 13.1 (10.67)		
Week 4 chg		53 -19.4 (12.85)	-19.38 (1.28)		57 -20.1 (11.53)	-20.22 (1.24)	-0.84 (-4.36, 2.68) 0.639 [-0.07 (-0.44, 0.31)]
Week 6		52 12.4 (11.99)			56 10.3 (8.63)		
Week 6 chg		52 -21.0 (12.46)	-21.14 (1.29)		56 -22.9 (11.93)	-22.97 (1.25)	-1.84 (-5.37, 1.70) 0.306 [-0.15 (-0.53, 0.23)]
Week 8		52 12.4 (12.69)			54 7.8 (6.31)		
Week 8 chg		52 -21.0 (14.93)	-21.13 (1.29)		54 -25.3 (12.72)	-25.39 (1.25)	-4.25 (-7.80, -0.70) 0.019 [-0.31 (-0.69, 0.08)]
Week 10		52 10.6 (11.25)			54 7.0 (6.92)		
Week 10 chg		52 -22.8 (14.62)	-22.93 (1.29)		54 -26.2 (12.43)	-26.09 (1.25)	-3.16 (-6.71, 0.38) 0.080 [-0.23 (-0.62, 0.15)]
Week 12		51 11.0 (11.52)			53 6.7 (6.69)		
Week 12 chg		51 -22.6 (15.95)	-22.81 (1.29)		53 -26.8 (12.05)	-26.52 (1.26)	-3.70 (-7.26, -0.14) 0.041 [-0.26 (-0.65, 0.12)]
Week 14		51 9.7 (11.64)			53 5.0 (5.79)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3823
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.401.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	51	-23.8 (16.37)	-24.03 (1.29)	53	-27.9 (12.60)	-27.92 (1.26)	-3.89 (-7.45, -0.33) [-0.27 (-0.65, 0.12)]	0.032
Week 16	48	9.5 (12.99)		50	5.6 (7.06)			
Week 16 chg	48	-24.6 (17.73)	-24.14 (1.31)	50	-28.1 (13.46)	-27.29 (1.27)	-3.15 (-6.75, 0.45) [-0.20 (-0.60, 0.20)]	0.086

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3823
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.401.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 34.3 (12.71)		81	81 31.3 (10.94)		
Week 2		83 21.9 (13.69)			81 19.4 (12.59)		
Week 2 chg		83 -12.3 (11.64)	-11.65 (1.07)		81 -11.9 (10.39)	-12.60 (1.09)	-0.94 (-3.98, 2.09) 0.541 [-0.09 (-0.39, 0.22)]
Week 4		81 16.8 (12.63)			80 13.1 (10.22)		
Week 4 chg		81 -17.4 (11.30)	-16.25 (1.08)		80 -17.9 (9.83)	-18.74 (1.09)	-2.49 (-5.54, 0.56) 0.109 [-0.23 (-0.54, 0.08)]
Week 6		80 16.2 (12.51)			78 11.8 (10.36)		
Week 6 chg		80 -18.1 (12.67)	-16.62 (1.08)		78 -19.4 (11.79)	-20.37 (1.10)	-3.75 (-6.81, -0.69) 0.017 [-0.31 (-0.62, 0.01)]
Week 8		81 15.0 (12.72)			76 10.9 (9.58)		
Week 8 chg		81 -19.2 (13.15)	-17.97 (1.08)		76 -20.5 (11.42)	-21.46 (1.11)	-3.49 (-6.55, -0.42) 0.026 [-0.28 (-0.60, 0.03)]
Week 10		79 13.8 (11.84)			76 8.1 (7.79)		
Week 10 chg		79 -20.6 (13.48)	-18.90 (1.09)		76 -22.9 (10.74)	-24.17 (1.11)	-5.28 (-8.35, -2.20) <.001 [-0.43 (-0.75, -0.11)]
Week 12		77 12.7 (11.01)			75 8.3 (8.55)		
Week 12 chg		77 -21.9 (13.13)	-19.75 (1.09)		75 -23.2 (12.50)	-24.15 (1.11)	-4.40 (-7.48, -1.31) 0.005 [-0.34 (-0.66, -0.02)]
Week 14		75 12.3 (11.48)			74 8.4 (9.56)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3823
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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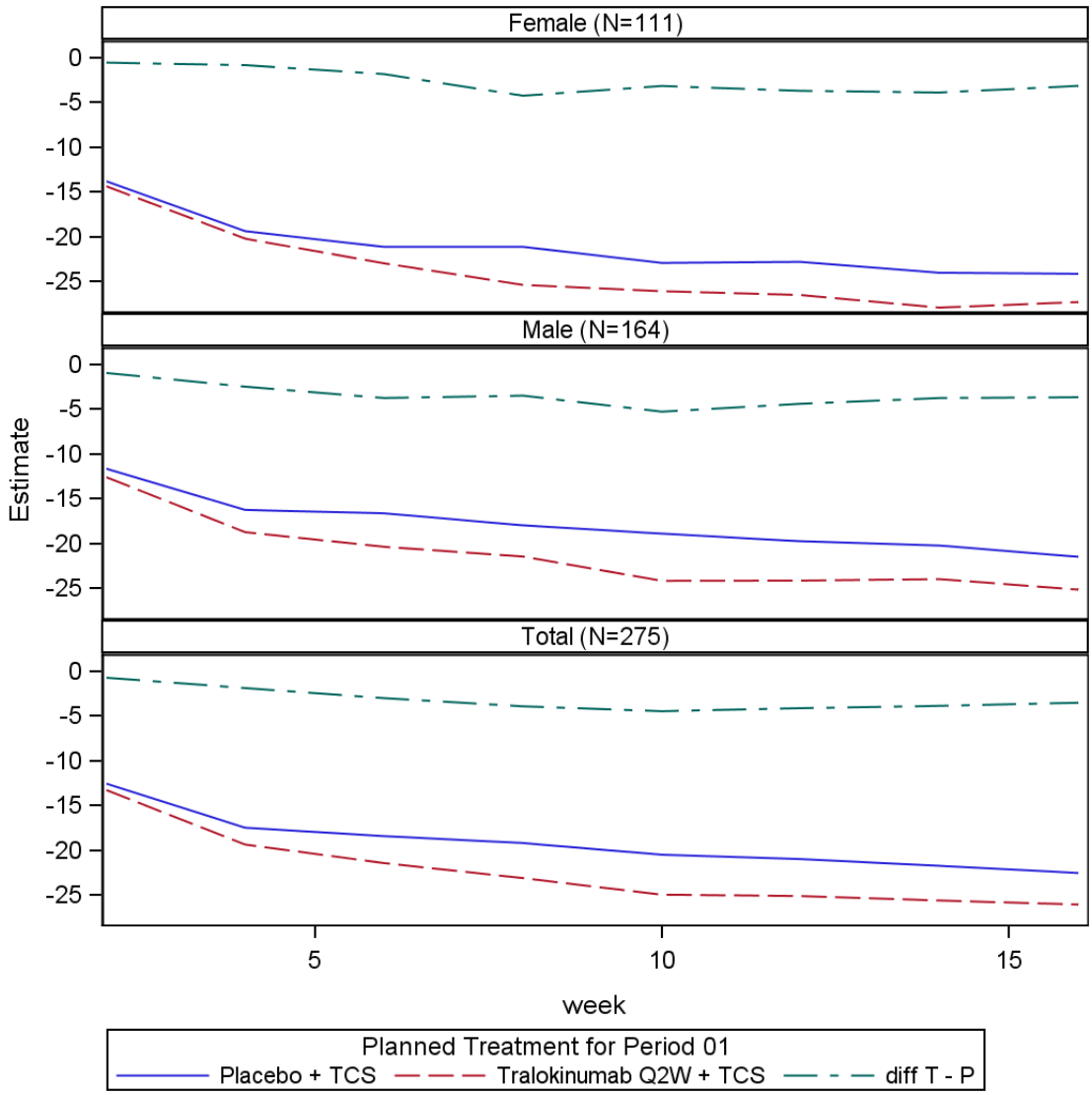
Table 1.4.401.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	75	-22.1 (13.51)	-20.23 (1.10)	74	-23.1 (13.48)	-23.98 (1.11)	-3.75 (-6.85, -0.66) [-0.28 (-0.60, 0.04)]	0.018
Week 16	76	11.2 (10.34)		73	6.9 (8.01)			
Week 16 chg	76	-23.3 (12.96)	-21.49 (1.10)	73	-24.3 (12.14)	-25.16 (1.11)	-3.67 (-6.76, -0.57) [-0.29 (-0.61, 0.03)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3823
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.401.4.2: Total, Gender, change in EASI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.4.403.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)										
Total										
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)			
Week 1		135	6.3 (1.69)			136	6.0 (1.78)			
Week 1 chg		135	-1.1 (1.34)	-1.14 (0.17)		136	-1.2 (1.31)	-1.23 (0.17)	-0.08 (-0.56, 0.39) [-0.06 (-0.30, 0.18)]	0.732
Week 2		134	5.8 (1.97)			132	5.4 (2.11)			
Week 2 chg		134	-1.7 (1.78)	-1.67 (0.17)		132	-1.9 (1.67)	-1.92 (0.17)	-0.24 (-0.72, 0.24) [-0.14 (-0.38, 0.10)]	0.324
Week 3		133	5.3 (2.17)			131	4.8 (2.08)			
Week 3 chg		133	-2.2 (2.12)	-2.11 (0.17)		131	-2.5 (1.84)	-2.53 (0.17)	-0.42 (-0.90, 0.06) [-0.21 (-0.45, 0.03)]	0.088
Week 4		130	5.1 (2.25)			133	4.4 (2.14)			
Week 4 chg		130	-2.4 (2.14)	-2.29 (0.17)		133	-2.8 (1.92)	-2.87 (0.17)	-0.58 (-1.06, -0.10) [-0.28 (-0.53, -0.04)]	0.019
Week 5		131	4.9 (2.37)			129	4.2 (2.15)			
Week 5 chg		131	-2.6 (2.26)	-2.54 (0.17)		129	-3.1 (1.92)	-3.16 (0.17)	-0.62 (-1.10, -0.14) [-0.30 (-0.54, -0.05)]	0.012
Week 6		130	4.8 (2.35)			129	4.2 (2.16)			
Week 6 chg		130	-2.7 (2.25)	-2.58 (0.17)		129	-3.1 (1.99)	-3.14 (0.17)	-0.57 (-1.05, -0.08) [-0.27 (-0.51, -0.02)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0030
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.403.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	4.7 (2.24)		128	4.0 (2.13)		
Week 7 chg	129	-2.8 (2.25)	-2.73 (0.17)	128	-3.3 (2.05)	-3.38 (0.17)	-0.65 (-1.13, -0.16) 0.009 [-0.30 (-0.55, -0.05)]
Week 8	127	4.7 (2.32)		125	3.7 (2.10)		
Week 8 chg	127	-2.8 (2.27)	-2.73 (0.17)	125	-3.7 (1.96)	-3.64 (0.17)	-0.92 (-1.40, -0.43) <.001 [-0.43 (-0.68, -0.18)]
Week 9	127	4.6 (2.37)		127	3.6 (2.10)		
Week 9 chg	127	-2.9 (2.32)	-2.79 (0.17)	127	-3.7 (2.03)	-3.71 (0.17)	-0.92 (-1.40, -0.44) <.001 [-0.42 (-0.67, -0.17)]
Week 10	125	4.5 (2.42)		122	3.6 (2.11)		
Week 10 chg	125	-2.9 (2.39)	-2.87 (0.17)	122	-3.7 (1.93)	-3.70 (0.17)	-0.83 (-1.32, -0.35) <.001 [-0.38 (-0.63, -0.13)]
Week 11	128	4.4 (2.41)		126	3.5 (2.15)		
Week 11 chg	128	-3.1 (2.40)	-3.06 (0.17)	126	-3.7 (1.97)	-3.75 (0.17)	-0.70 (-1.18, -0.21) 0.005 [-0.32 (-0.56, -0.07)]
Week 12	123	4.4 (2.36)		121	3.5 (2.08)		
Week 12 chg	123	-3.1 (2.41)	-3.03 (0.17)	121	-3.8 (2.06)	-3.82 (0.17)	-0.80 (-1.28, -0.31) 0.001 [-0.35 (-0.61, -0.10)]
Week 13	116	4.3 (2.38)		120	3.3 (2.06)		
Week 13 chg	116	-3.3 (2.35)	-3.09 (0.18)	120	-4.0 (2.09)	-3.92 (0.17)	-0.84 (-1.32, -0.35) <.001 [-0.38 (-0.63, -0.12)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0030
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.403.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.13 (0.17)	123	-3.9 (2.12)	-3.85 (0.17)	-0.72 (-1.20, -0.23) [-0.32 (-0.57, -0.07)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.16 (0.17)	123	-4.0 (2.15)	-3.93 (0.17)	-0.76 (-1.25, -0.28) [-0.34 (-0.59, -0.09)]	0.002
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.10 (0.17)	122	-3.9 (2.06)	-3.93 (0.17)	-0.83 (-1.32, -0.35) [-0.38 (-0.63, -0.12)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0030
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.403.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 7.7 (1.40)		57	57 7.6 (1.42)		
Week 1		53 6.4 (1.87)			56 6.4 (1.63)		
Week 1 chg		53 -1.3 (1.42)	-1.30 (0.30)		56 -1.2 (1.34)	-1.18 (0.29)	0.12 (-0.71, 0.94) 0.783 [0.08 (-0.29, 0.46)]
Week 2		53 5.8 (2.11)			57 5.9 (2.03)		
Week 2 chg		53 -1.8 (1.75)	-1.83 (0.30)		57 -1.7 (1.64)	-1.73 (0.29)	0.09 (-0.73, 0.92) 0.821 [0.06 (-0.32, 0.43)]
Week 3		52 5.3 (2.38)			57 5.1 (2.09)		
Week 3 chg		52 -2.4 (2.25)	-2.37 (0.30)		57 -2.5 (1.91)	-2.53 (0.29)	-0.16 (-0.99, 0.67) 0.703 [-0.08 (-0.45, 0.30)]
Week 4		52 4.9 (2.54)			57 4.7 (2.29)		
Week 4 chg		52 -2.8 (2.36)	-2.72 (0.30)		57 -2.9 (2.14)	-2.90 (0.29)	-0.18 (-1.01, 0.65) 0.670 [-0.08 (-0.46, 0.30)]
Week 5		52 4.7 (2.68)			55 4.3 (2.22)		
Week 5 chg		52 -2.9 (2.49)	-2.88 (0.30)		55 -3.3 (2.11)	-3.41 (0.29)	-0.53 (-1.36, 0.30) 0.208 [-0.23 (-0.61, 0.15)]
Week 6		51 4.7 (2.59)			55 4.4 (2.22)		
Week 6 chg		51 -3.1 (2.48)	-2.97 (0.30)		55 -3.2 (2.23)	-3.30 (0.29)	-0.33 (-1.17, 0.50) 0.428 [-0.14 (-0.52, 0.24)]
Week 7		51 4.7 (2.41)			54 4.2 (2.25)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
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Table 1.4.403.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	51	-3.1 (2.40)	-2.97 (0.30)	54	-3.5 (2.30)	-3.52 (0.29)	-0.55 (-1.38, 0.28) [-0.23 (-0.62, 0.15)]	0.195
Week 8	50	4.6 (2.45)		54	3.8 (2.19)			
Week 8 chg	50	-3.2 (2.45)	-3.06 (0.30)	54	-3.9 (2.19)	-3.92 (0.29)	-0.86 (-1.69, -0.03) [-0.37 (-0.76, 0.02)]	0.043
Week 9	50	4.6 (2.56)		54	3.7 (2.23)			
Week 9 chg	50	-3.1 (2.51)	-3.07 (0.30)	54	-4.0 (2.25)	-4.00 (0.29)	-0.93 (-1.76, -0.10) [-0.39 (-0.78, -0.00)]	0.029
Week 10	49	4.4 (2.55)		53	3.8 (2.17)			
Week 10 chg	49	-3.3 (2.53)	-3.23 (0.30)	53	-3.9 (2.15)	-3.94 (0.29)	-0.71 (-1.55, 0.12) [-0.30 (-0.70, 0.09)]	0.093
Week 11	50	4.2 (2.54)		53	3.7 (2.29)			
Week 11 chg	50	-3.5 (2.51)	-3.46 (0.30)	53	-3.9 (2.25)	-4.00 (0.29)	-0.54 (-1.38, 0.29) [-0.23 (-0.62, 0.16)]	0.199
Week 12	48	4.1 (2.69)		53	3.7 (2.22)			
Week 12 chg	48	-3.6 (2.71)	-3.54 (0.30)	53	-4.0 (2.37)	-4.04 (0.29)	-0.50 (-1.34, 0.33) [-0.20 (-0.59, 0.19)]	0.236
Week 13	48	3.9 (2.56)		51	3.3 (2.33)			
Week 13 chg	48	-3.8 (2.61)	-3.70 (0.30)	51	-4.3 (2.48)	-4.26 (0.29)	-0.56 (-1.40, 0.28) [-0.22 (-0.62, 0.18)]	0.189
Week 14	49	3.8 (2.55)		53	3.5 (2.41)			

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Table 1.4.403.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	49	-3.9 (2.59)	-3.78 (0.30)	53	-4.1 (2.57)	-4.13 (0.29)	-0.35 (-1.18, 0.48) [-0.14 (-0.52, 0.25)]	0.408
Week 15	49	4.0 (2.51)		53	3.4 (2.48)			
Week 15 chg	49	-3.8 (2.54)	-3.67 (0.30)	53	-4.3 (2.64)	-4.27 (0.29)	-0.60 (-1.44, 0.23) [-0.23 (-0.62, 0.16)]	0.156
Week 16	50	3.8 (2.42)		52	3.4 (2.39)			
Week 16 chg	50	-3.9 (2.55)	-3.73 (0.30)	52	-4.2 (2.45)	-4.27 (0.29)	-0.53 (-1.37, 0.30) [-0.21 (-0.60, 0.18)]	0.208

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0030
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Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 7.3 (1.34)		81	80 7.0 (1.43)		
Week 1		82 6.3 (1.58)			80 5.8 (1.85)		
Week 1 chg		82 -1.0 (1.28)	-1.03 (0.21)		80 -1.2 (1.30)	-1.27 (0.21)	-0.24 (-0.82, 0.34) 0.414 [-0.19 (-0.50, 0.12)]
Week 2		81 5.7 (1.89)			75 5.0 (2.09)		
Week 2 chg		81 -1.6 (1.80)	-1.55 (0.21)		75 -2.0 (1.69)	-2.09 (0.21)	-0.54 (-1.12, 0.05) 0.070 [-0.31 (-0.62, 0.01)]
Week 3		81 5.4 (2.03)			74 4.5 (2.04)		
Week 3 chg		81 -2.0 (2.02)	-1.93 (0.21)		74 -2.5 (1.79)	-2.56 (0.21)	-0.63 (-1.21, -0.05) 0.035 [-0.33 (-0.65, -0.01)]
Week 4		78 5.3 (2.04)			76 4.2 (2.01)		
Week 4 chg		78 -2.1 (1.95)	-1.99 (0.21)		76 -2.8 (1.75)	-2.86 (0.21)	-0.87 (-1.45, -0.28) 0.004 [-0.47 (-0.79, -0.15)]
Week 5		79 5.0 (2.15)			74 4.1 (2.11)		
Week 5 chg		79 -2.4 (2.09)	-2.30 (0.21)		74 -2.9 (1.77)	-2.99 (0.21)	-0.69 (-1.27, -0.10) 0.022 [-0.35 (-0.67, -0.03)]
Week 6		79 4.9 (2.18)			74 4.0 (2.11)		
Week 6 chg		79 -2.4 (2.06)	-2.32 (0.21)		74 -3.0 (1.79)	-3.03 (0.21)	-0.71 (-1.30, -0.13) 0.017 [-0.37 (-0.69, -0.05)]
Week 7		78 4.7 (2.14)			74 3.8 (2.04)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0030
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Table 1.4.403.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	78		-2.7 (2.14)	-2.56	(0.21)	74		-3.2 (1.86)	-3.29	(0.21)	-0.72 (-1.31, -0.14) 0.016 [-0.36 (-0.68, -0.04)]
Week 8	77		4.7 (2.25)			71		3.6 (2.04)			
Week 8 chg	77		-2.6 (2.13)	-2.50	(0.21)	71		-3.5 (1.75)	-3.44	(0.21)	-0.94 (-1.52, -0.35) 0.002 [-0.48 (-0.81, -0.15)]
Week 9	77		4.7 (2.26)			73		3.6 (2.02)			
Week 9 chg	77		-2.7 (2.20)	-2.60	(0.21)	73		-3.5 (1.84)	-3.50	(0.21)	-0.90 (-1.49, -0.32) 0.003 [-0.45 (-0.77, -0.12)]
Week 10	76		4.7 (2.34)			69		3.5 (2.07)			
Week 10 chg	76		-2.7 (2.27)	-2.63	(0.21)	69		-3.5 (1.75)	-3.54	(0.21)	-0.90 (-1.49, -0.32) 0.003 [-0.44 (-0.77, -0.11)]
Week 11	78		4.5 (2.33)			73		3.4 (2.05)			
Week 11 chg	78		-2.9 (2.30)	-2.79	(0.21)	73		-3.6 (1.75)	-3.58	(0.21)	-0.79 (-1.38, -0.20) 0.009 [-0.38 (-0.71, -0.06)]
Week 12	75		4.5 (2.13)			68		3.4 (1.97)			
Week 12 chg	75		-2.8 (2.16)	-2.69	(0.21)	68		-3.6 (1.78)	-3.67	(0.21)	-0.99 (-1.58, -0.40) 0.001 [-0.50 (-0.83, -0.16)]
Week 13	68		4.6 (2.22)			69		3.3 (1.86)			
Week 13 chg	68		-2.9 (2.09)	-2.68	(0.21)	69		-3.7 (1.72)	-3.68	(0.21)	-1.00 (-1.59, -0.41) 0.001 [-0.52 (-0.86, -0.18)]
Week 14	74		4.5 (2.24)			70		3.3 (1.90)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0030
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.403.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	74	-2.9 (2.07)	-2.70 (0.21)	70	-3.7 (1.70)	-3.63 (0.21)	-0.93 (-1.52, -0.34) [-0.49 (-0.82, -0.16)]	0.002
Week 15	74	4.4 (2.17)		70	3.3 (1.79)			
Week 15 chg	74	-3.0 (2.13)	-2.83 (0.21)	70	-3.7 (1.66)	-3.68 (0.21)	-0.85 (-1.44, -0.26) [-0.44 (-0.77, -0.11)]	0.005
Week 16	71	4.5 (2.16)		70	3.3 (1.78)			
Week 16 chg	71	-2.9 (2.11)	-2.67 (0.21)	70	-3.7 (1.71)	-3.70 (0.21)	-1.02 (-1.62, -0.43) [-0.53 (-0.87, -0.20)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0030
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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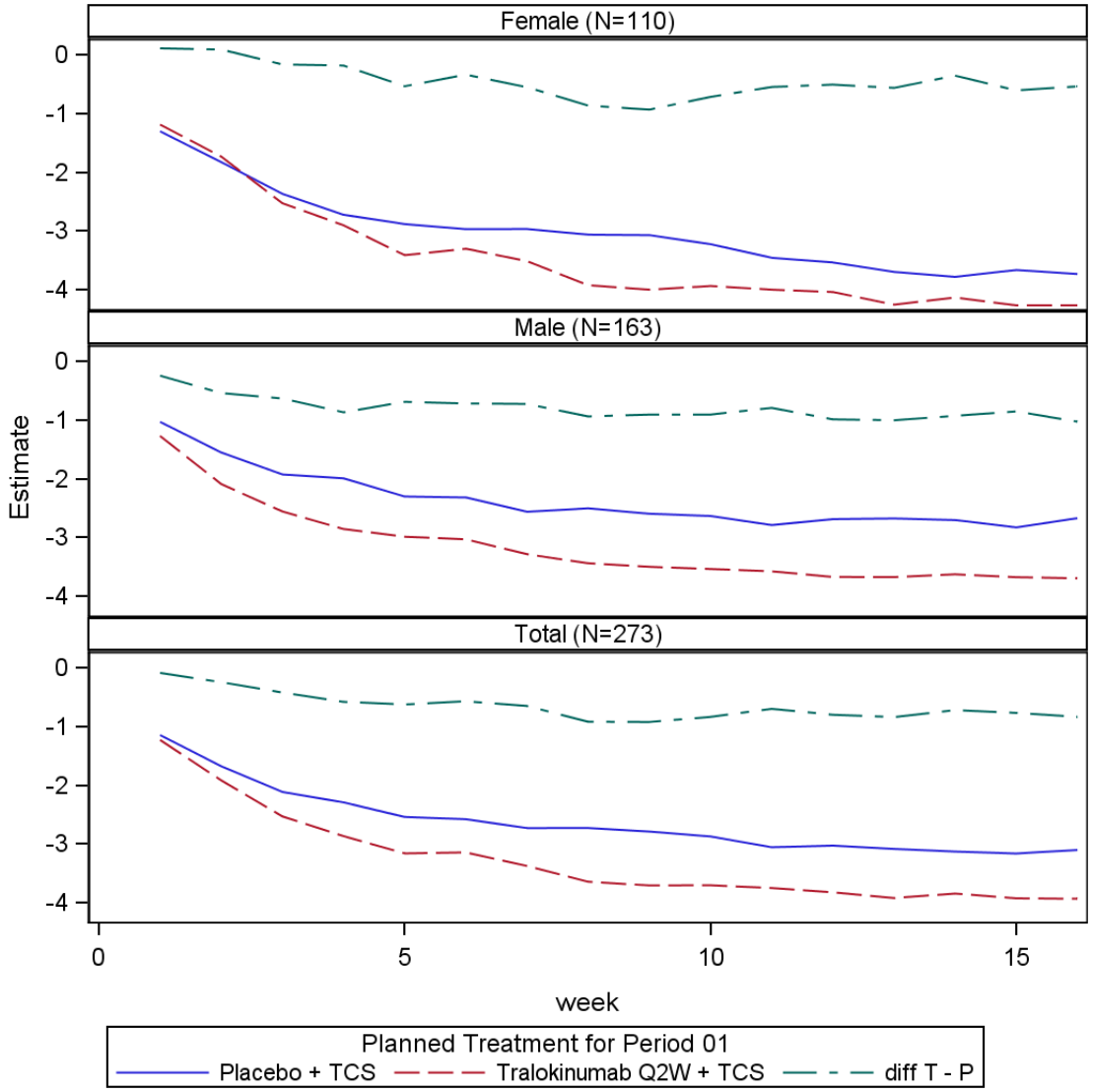
Figure 1.4.403.4.2: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16



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 Prior CSA use, 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 1.4.405.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 1		135 5.8 (2.01)			136 5.2 (2.21)		
Week 1 chg		135 -1.1 (1.50)	-1.07 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.08 (-0.58, 0.42) 0.756 [-0.05 (-0.29, 0.18)]
Week 2		134 5.2 (2.29)			132 4.5 (2.45)		
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.18)	-0.18 (-0.68, 0.33) 0.493 [-0.09 (-0.33, 0.15)]
Week 3		133 4.7 (2.36)			131 3.9 (2.35)		
Week 3 chg		133 -2.2 (2.17)	-2.13 (0.18)		131 -2.4 (2.01)	-2.49 (0.18)	-0.36 (-0.86, 0.14) 0.160 [-0.17 (-0.41, 0.07)]
Week 4		130 4.5 (2.48)			133 3.6 (2.39)		
Week 4 chg		130 -2.4 (2.23)	-2.26 (0.18)		133 -2.7 (2.06)	-2.79 (0.18)	-0.53 (-1.03, -0.03) 0.038 [-0.25 (-0.49, -0.01)]
Week 5		131 4.2 (2.55)			129 3.3 (2.42)		
Week 5 chg		131 -2.7 (2.37)	-2.56 (0.18)		129 -3.0 (2.16)	-3.14 (0.18)	-0.58 (-1.08, -0.07) 0.024 [-0.25 (-0.50, -0.01)]
Week 6		130 4.2 (2.52)			129 3.3 (2.42)		
Week 6 chg		130 -2.7 (2.36)	-2.53 (0.18)		129 -3.1 (2.24)	-3.20 (0.18)	-0.67 (-1.17, -0.17) 0.009 [-0.29 (-0.54, -0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0002
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.405.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	129 3.9 (2.43)		128	128 3.1 (2.37)			
Week 7 chg	129	129 -3.0 (2.38)	-2.81 (0.18)	128	128 -3.3 (2.28)	-3.41 (0.18)	-0.60 (-1.10, -0.10) [-0.26 (-0.50, -0.01)]	0.020
Week 8	127	127 3.9 (2.46)		125	125 2.8 (2.29)			
Week 8 chg	127	127 -3.0 (2.32)	-2.79 (0.18)	125	125 -3.6 (2.26)	-3.65 (0.18)	-0.86 (-1.36, -0.35) [-0.37 (-0.62, -0.12)]	<.001
Week 9	127	127 3.8 (2.49)		127	127 2.6 (2.22)			
Week 9 chg	127	127 -3.1 (2.33)	-2.92 (0.18)	127	127 -3.7 (2.23)	-3.83 (0.18)	-0.91 (-1.41, -0.40) [-0.40 (-0.65, -0.15)]	<.001
Week 10	125	125 3.7 (2.54)		122	122 2.7 (2.29)			
Week 10 chg	125	125 -3.2 (2.40)	-3.04 (0.18)	122	122 -3.7 (2.29)	-3.82 (0.18)	-0.79 (-1.29, -0.28) [-0.33 (-0.59, -0.08)]	0.002
Week 11	128	128 3.6 (2.46)		126	126 2.6 (2.22)			
Week 11 chg	128	128 -3.3 (2.40)	-3.15 (0.18)	126	126 -3.8 (2.26)	-3.89 (0.18)	-0.75 (-1.25, -0.24) [-0.32 (-0.57, -0.07)]	0.004
Week 12	123	123 3.5 (2.44)		121	121 2.5 (2.21)			
Week 12 chg	123	123 -3.4 (2.45)	-3.18 (0.18)	121	121 -3.8 (2.38)	-4.01 (0.18)	-0.82 (-1.33, -0.31) [-0.34 (-0.59, -0.09)]	0.002
Week 13	116	116 3.4 (2.40)		120	120 2.3 (2.13)			
Week 13 chg	116	116 -3.6 (2.32)	-3.32 (0.18)	120	120 -3.9 (2.26)	-4.05 (0.18)	-0.74 (-1.25, -0.23) [-0.32 (-0.58, -0.06)]	0.005

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0002
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.405.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	3.3 (2.42)		123	2.4 (2.18)			
Week 14 chg	123	-3.5 (2.33)	-3.36 (0.18)	123	-3.9 (2.27)	-4.03 (0.18)	-0.67 (-1.18, -0.16) [-0.29 (-0.54, -0.04)]	0.010
Week 15	123	3.3 (2.47)		123	2.4 (2.18)			
Week 15 chg	123	-3.7 (2.35)	-3.42 (0.18)	123	-3.9 (2.35)	-4.08 (0.18)	-0.66 (-1.16, -0.15) [-0.28 (-0.53, -0.03)]	0.011
Week 16	121	3.2 (2.40)		122	2.5 (2.17)			
Week 16 chg	121	-3.7 (2.28)	-3.41 (0.18)	122	-3.9 (2.32)	-4.06 (0.18)	-0.65 (-1.16, -0.14) [-0.28 (-0.54, -0.03)]	0.012

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0002
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.405.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 6.9 (1.84)		57	57 6.7 (2.11)		
Week 1		53 5.7 (2.34)			56 5.5 (2.16)		
Week 1 chg		53 -1.2 (1.59)	-1.19 (0.30)		56 -1.2 (1.54)	-1.21 (0.30)	-0.02 (-0.86, 0.82) 0.959 [-0.01 (-0.39, 0.36)]
Week 2		53 5.1 (2.52)			57 4.8 (2.54)		
Week 2 chg		53 -1.8 (2.02)	-1.81 (0.30)		57 -1.8 (1.82)	-1.85 (0.29)	-0.04 (-0.88, 0.80) 0.924 [-0.02 (-0.40, 0.35)]
Week 3		52 4.5 (2.60)			57 4.1 (2.44)		
Week 3 chg		52 -2.4 (2.22)	-2.34 (0.31)		57 -2.6 (2.15)	-2.64 (0.29)	-0.30 (-1.14, 0.54) 0.487 [-0.14 (-0.51, 0.24)]
Week 4		52 4.1 (2.80)			57 3.7 (2.54)		
Week 4 chg		52 -2.8 (2.36)	-2.69 (0.31)		57 -2.9 (2.23)	-2.98 (0.29)	-0.29 (-1.13, 0.55) 0.497 [-0.13 (-0.50, 0.25)]
Week 5		52 3.8 (2.84)			55 3.4 (2.48)		
Week 5 chg		52 -3.1 (2.50)	-2.99 (0.31)		55 -3.4 (2.37)	-3.50 (0.30)	-0.52 (-1.36, 0.32) 0.224 [-0.21 (-0.59, 0.17)]
Week 6		51 3.9 (2.75)			55 3.3 (2.47)		
Week 6 chg		51 -3.0 (2.48)	-2.90 (0.31)		55 -3.5 (2.55)	-3.56 (0.30)	-0.66 (-1.50, 0.18) 0.125 [-0.26 (-0.64, 0.12)]
Week 7		51 3.7 (2.67)			54 3.1 (2.48)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0002
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.405.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	51	-3.2 (2.50)	-3.13 (0.31)	54	-3.7 (2.47)	-3.74 (0.30)	-0.61 (-1.45, 0.24) 0.158 [-0.24 (-0.63, 0.14)]
Week 8	50	3.7 (2.67)		54	2.8 (2.39)		
Week 8 chg	50	-3.3 (2.45)	-3.13 (0.31)	54	-4.0 (2.46)	-4.04 (0.30)	-0.91 (-1.76, -0.07) 0.034 [-0.37 (-0.76, 0.02)]
Week 9	50	3.6 (2.63)		54	2.6 (2.29)		
Week 9 chg	50	-3.3 (2.38)	-3.28 (0.31)	54	-4.1 (2.48)	-4.24 (0.30)	-0.96 (-1.81, -0.12) 0.026 [-0.40 (-0.78, -0.01)]
Week 10	49	3.4 (2.66)		53	2.6 (2.28)		
Week 10 chg	49	-3.5 (2.36)	-3.37 (0.31)	53	-4.2 (2.51)	-4.29 (0.30)	-0.92 (-1.77, -0.07) 0.033 [-0.38 (-0.77, 0.02)]
Week 11	50	3.3 (2.62)		53	2.5 (2.39)		
Week 11 chg	50	-3.6 (2.43)	-3.58 (0.31)	53	-4.3 (2.59)	-4.31 (0.30)	-0.73 (-1.57, 0.12) 0.091 [-0.29 (-0.68, 0.10)]
Week 12	48	3.1 (2.61)		53	2.5 (2.43)		
Week 12 chg	48	-3.9 (2.57)	-3.74 (0.31)	53	-4.3 (2.75)	-4.33 (0.30)	-0.59 (-1.44, 0.26) 0.171 [-0.22 (-0.61, 0.17)]
Week 13	48	2.8 (2.46)		51	2.3 (2.36)		
Week 13 chg	48	-4.1 (2.36)	-3.98 (0.31)	51	-4.4 (2.66)	-4.38 (0.30)	-0.40 (-1.25, 0.45) 0.358 [-0.16 (-0.55, 0.24)]
Week 14	49	2.7 (2.38)		53	2.6 (2.42)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0002
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.405.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	49	-4.2 (2.39)	-4.11 (0.31)	53	-4.2 (2.71)	-4.26 (0.30)	-0.15 (-1.00, 0.69) 0.724 [-0.06 (-0.45, 0.33)]
Week 15	49	2.7 (2.59)		53	2.5 (2.52)		
Week 15 chg	49	-4.3 (2.39)	-4.06 (0.31)	53	-4.2 (2.82)	-4.32 (0.30)	-0.26 (-1.11, 0.59) 0.547 [-0.10 (-0.49, 0.29)]
Week 16	50	2.6 (2.46)		52	2.5 (2.42)		
Week 16 chg	50	-4.3 (2.28)	-4.09 (0.31)	52	-4.2 (2.68)	-4.35 (0.30)	-0.26 (-1.10, 0.59) 0.549 [-0.10 (-0.49, 0.29)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0002
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.405.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 6.9 (1.52)		81	80 6.1 (2.08)		
Week 1		82 5.9 (1.78)			80 5.0 (2.23)		
Week 1 chg		82 -1.1 (1.44)	-0.97 (0.22)		80 -1.0 (1.40)	-1.13 (0.22)	-0.16 (-0.78, 0.46) 0.616 [-0.11 (-0.42, 0.20)]
Week 2		81 5.2 (2.14)			75 4.3 (2.38)		
Week 2 chg		81 -1.7 (1.97)	-1.54 (0.22)		75 -1.7 (1.80)	-1.89 (0.22)	-0.35 (-0.97, 0.27) 0.270 [-0.19 (-0.50, 0.13)]
Week 3		81 4.8 (2.20)			74 3.8 (2.28)		
Week 3 chg		81 -2.1 (2.15)	-1.96 (0.22)		74 -2.3 (1.89)	-2.41 (0.22)	-0.45 (-1.08, 0.17) 0.153 [-0.22 (-0.54, 0.09)]
Week 4		78 4.8 (2.23)			76 3.5 (2.28)		
Week 4 chg		78 -2.2 (2.11)	-1.94 (0.22)		76 -2.5 (1.92)	-2.69 (0.22)	-0.74 (-1.37, -0.12) 0.020 [-0.37 (-0.69, -0.05)]
Week 5		79 4.4 (2.32)			74 3.3 (2.39)		
Week 5 chg		79 -2.5 (2.26)	-2.26 (0.22)		74 -2.7 (1.95)	-2.88 (0.22)	-0.62 (-1.24, 0.01) 0.052 [-0.29 (-0.61, 0.03)]
Week 6		79 4.4 (2.35)			74 3.3 (2.41)		
Week 6 chg		79 -2.5 (2.27)	-2.29 (0.22)		74 -2.8 (1.94)	-2.93 (0.22)	-0.64 (-1.27, -0.02) 0.044 [-0.30 (-0.62, 0.02)]
Week 7		78 4.1 (2.26)			74 3.1 (2.30)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0002
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.405.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	78	-2.8 (2.31)	-2.58 (0.22)	74	-3.0 (2.09)	-3.19 (0.22)	-0.61 (-1.23, 0.02) 0.057 [-0.28 (-0.60, 0.04)]
Week 8	77	4.1 (2.32)		71	2.9 (2.22)		
Week 8 chg	77	-2.8 (2.22)	-2.57 (0.22)	71	-3.2 (2.05)	-3.37 (0.22)	-0.81 (-1.43, -0.18) 0.012 [-0.38 (-0.70, -0.05)]
Week 9	77	4.0 (2.39)		73	2.7 (2.17)		
Week 9 chg	77	-3.0 (2.31)	-2.70 (0.22)	73	-3.4 (1.99)	-3.54 (0.22)	-0.84 (-1.47, -0.22) 0.009 [-0.39 (-0.71, -0.07)]
Week 10	76	3.9 (2.46)		69	2.8 (2.32)		
Week 10 chg	76	-3.0 (2.43)	-2.82 (0.22)	69	-3.3 (2.04)	-3.48 (0.23)	-0.66 (-1.29, -0.03) 0.039 [-0.29 (-0.62, 0.03)]
Week 11	78	3.8 (2.34)		73	2.6 (2.09)		
Week 11 chg	78	-3.1 (2.36)	-2.86 (0.22)	73	-3.4 (1.92)	-3.60 (0.22)	-0.74 (-1.37, -0.11) 0.021 [-0.34 (-0.66, -0.02)]
Week 12	75	3.8 (2.30)		68	2.5 (2.05)		
Week 12 chg	75	-3.1 (2.34)	-2.82 (0.22)	68	-3.4 (1.97)	-3.77 (0.23)	-0.95 (-1.58, -0.32) 0.003 [-0.44 (-0.77, -0.10)]
Week 13	68	3.8 (2.29)		69	2.4 (1.95)		
Week 13 chg	68	-3.2 (2.24)	-2.86 (0.22)	69	-3.6 (1.88)	-3.82 (0.23)	-0.96 (-1.60, -0.33) 0.003 [-0.47 (-0.81, -0.13)]
Week 14	74	3.8 (2.35)		70	2.3 (1.99)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0002
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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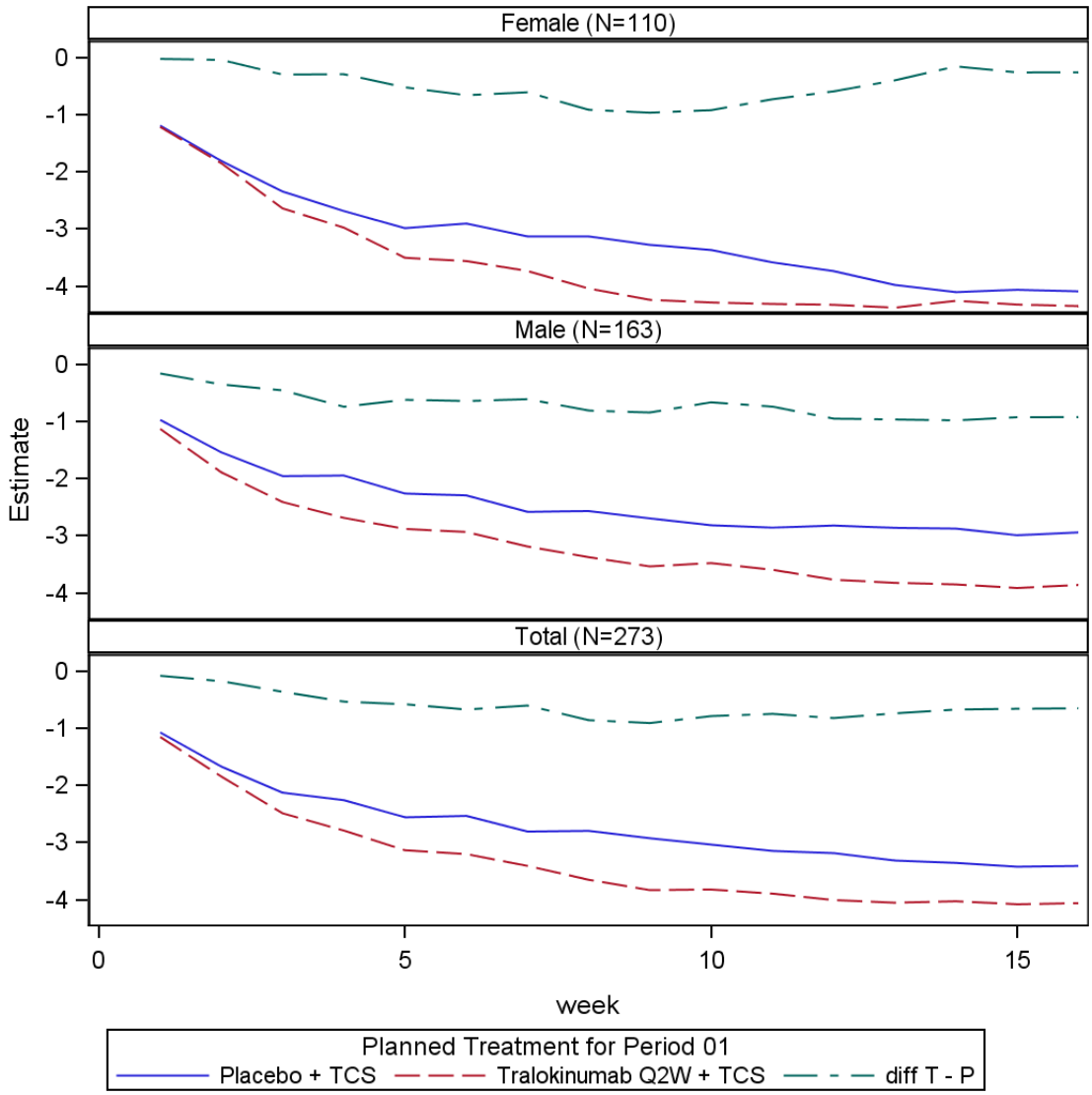
Table 1.4.405.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	74	-3.1 (2.21)	-2.87 (0.22)	70	-3.7 (1.87)	-3.85 (0.23)	-0.98 (-1.61, -0.35) [-0.48 (-0.81, -0.15)]	0.002
Week 15	74	3.7 (2.33)		70	2.3 (1.91)			
Week 15 chg	74	-3.3 (2.27)	-2.99 (0.22)	70	-3.7 (1.90)	-3.91 (0.23)	-0.92 (-1.55, -0.29) [-0.44 (-0.77, -0.11)]	0.004
Week 16	71	3.7 (2.27)		70	2.4 (1.99)			
Week 16 chg	71	-3.3 (2.20)	-2.94 (0.22)	70	-3.7 (2.01)	-3.86 (0.22)	-0.92 (-1.55, -0.29) [-0.44 (-0.77, -0.10)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0002
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.405.4.2: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.4.407.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.22 (1.49)		138 -20.9 (16.72)	-21.06 (1.48)	-3.84 (-7.97, 0.30) 0.069 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.25 (1.50)		137 -30.8 (17.25)	-31.00 (1.49)	-4.75 (-8.90, -0.60) 0.025 [-0.27 (-0.51, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.77 (1.50)		134 -34.3 (17.49)	-34.45 (1.49)	-7.67 (-11.8, -3.51) <.001 [-0.42 (-0.66, -0.18)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.63 (1.50)		130 -36.6 (18.48)	-36.80 (1.50)	-8.16 (-12.3, -3.99) <.001 [-0.43 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.78 (1.50)		130 -38.5 (19.49)	-38.59 (1.50)	-7.81 (-12.0, -3.63) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.51 (1.51)		128 -39.5 (18.74)	-39.57 (1.51)	-8.06 (-12.3, -3.87) <.001 [-0.42 (-0.67, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1575
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.407.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 36.0 (19.61)			127 28.3 (17.87)		
Week 14 chg		126 -34.8 (20.31)	-34.13 (1.52)		127 -41.8 (20.11)	-41.35 (1.51)	-7.22 (-11.4, -3.01) <.001 [-0.36 (-0.61, -0.11)]
Week 16		124 36.3 (18.78)			123 27.0 (16.90)		
Week 16 chg		124 -34.7 (19.94)	-33.86 (1.52)		123 -43.3 (19.46)	-42.65 (1.52)	-8.79 (-13.0, -4.57) <.001 [-0.45 (-0.70, -0.19)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1575
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.407.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 72.0 (13.89)		57	57 71.2 (11.89)		
Week 2		54 51.2 (19.83)			57 49.9 (18.26)		
Week 2 chg		54 -20.9 (16.80)	-20.65 (2.38)		57 -21.3 (17.56)	-21.59 (2.31)	-0.94 (-7.49, 5.61) 0.777 [-0.05 (-0.43, 0.32)]
Week 4		53 39.7 (18.34)			57 39.1 (17.96)		
Week 4 chg		53 -32.5 (17.59)	-31.95 (2.39)		57 -32.0 (17.88)	-32.45 (2.31)	-0.51 (-7.07, 6.06) 0.879 [-0.03 (-0.40, 0.35)]
Week 6		52 39.6 (18.46)			56 34.9 (16.90)		
Week 6 chg		52 -32.6 (18.93)	-32.18 (2.40)		56 -36.4 (18.50)	-36.52 (2.32)	-4.34 (-10.9, 2.25) 0.195 [-0.23 (-0.61, 0.15)]
Week 8		52 38.1 (21.15)			54 30.9 (15.55)		
Week 8 chg		52 -34.0 (20.66)	-33.64 (2.40)		54 -40.5 (17.74)	-40.22 (2.34)	-6.58 (-13.2, 0.03) 0.051 [-0.34 (-0.73, 0.04)]
Week 10		52 35.5 (20.36)			54 30.9 (17.80)		
Week 10 chg		52 -36.6 (20.85)	-36.21 (2.40)		54 -40.6 (20.25)	-40.35 (2.34)	-4.15 (-10.8, 2.46) 0.217 [-0.20 (-0.58, 0.18)]
Week 12		51 35.8 (19.18)			53 29.1 (16.11)		
Week 12 chg		51 -36.5 (21.25)	-36.42 (2.41)		53 -42.5 (16.83)	-42.27 (2.35)	-5.86 (-12.5, 0.77) 0.083 [-0.31 (-0.69, 0.08)]
Week 14		51 32.1 (21.19)			53 24.9 (14.57)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1575
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.407.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	51	-39.8 (21.32)	-40.05 (2.41)	53	-46.8 (18.11)	-45.90 (2.35)	-5.85 (-12.5, 0.78) [-0.30 (-0.68, 0.09)]	0.083
Week 16	48	31.9 (20.57)		50	25.7 (16.80)			
Week 16 chg	48	-39.9 (21.41)	-39.50 (2.43)	50	-46.3 (20.53)	-45.40 (2.37)	-5.90 (-12.6, 0.80) [-0.28 (-0.68, 0.12)]	0.084

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1575
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.407.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 70.0 (12.13)		81	81 69.5 (12.18)		
Week 2		83 54.8 (15.99)			81 48.9 (18.25)		
Week 2 chg		83 -15.3 (15.27)	-14.86 (1.89)		81 -20.6 (16.21)	-20.77 (1.91)	-5.91 (-11.2, -0.62) 0.029 [-0.38 (-0.68, -0.07)]
Week 4		81 46.5 (17.94)			80 39.2 (17.52)		
Week 4 chg		81 -23.2 (18.15)	-22.42 (1.90)		80 -30.0 (16.85)	-30.06 (1.91)	-7.63 (-12.9, -2.32) 0.005 [-0.44 (-0.75, -0.12)]
Week 6		80 45.9 (18.92)			78 36.4 (16.53)		
Week 6 chg		80 -24.1 (18.66)	-23.15 (1.90)		78 -32.7 (16.68)	-33.07 (1.93)	-9.92 (-15.2, -4.58) <.001 [-0.56 (-0.88, -0.24)]
Week 8		81 43.8 (19.19)			76 35.2 (17.81)		
Week 8 chg		81 -25.9 (18.83)	-25.28 (1.90)		76 -33.9 (18.62)	-34.45 (1.94)	-9.18 (-14.5, -3.84) <.001 [-0.49 (-0.81, -0.17)]
Week 10		79 41.7 (19.42)			76 31.7 (18.56)		
Week 10 chg		79 -28.2 (20.75)	-27.13 (1.91)		76 -37.0 (18.92)	-37.44 (1.94)	-10.30 (-15.7, -4.95) <.001 [-0.52 (-0.84, -0.20)]
Week 12		77 40.4 (17.45)			75 31.5 (18.71)		
Week 12 chg		77 -29.8 (18.15)	-28.21 (1.92)		75 -37.4 (19.83)	-37.75 (1.94)	-9.54 (-14.9, -4.17) <.001 [-0.50 (-0.83, -0.18)]
Week 14		75 38.7 (18.13)			74 30.7 (19.64)		

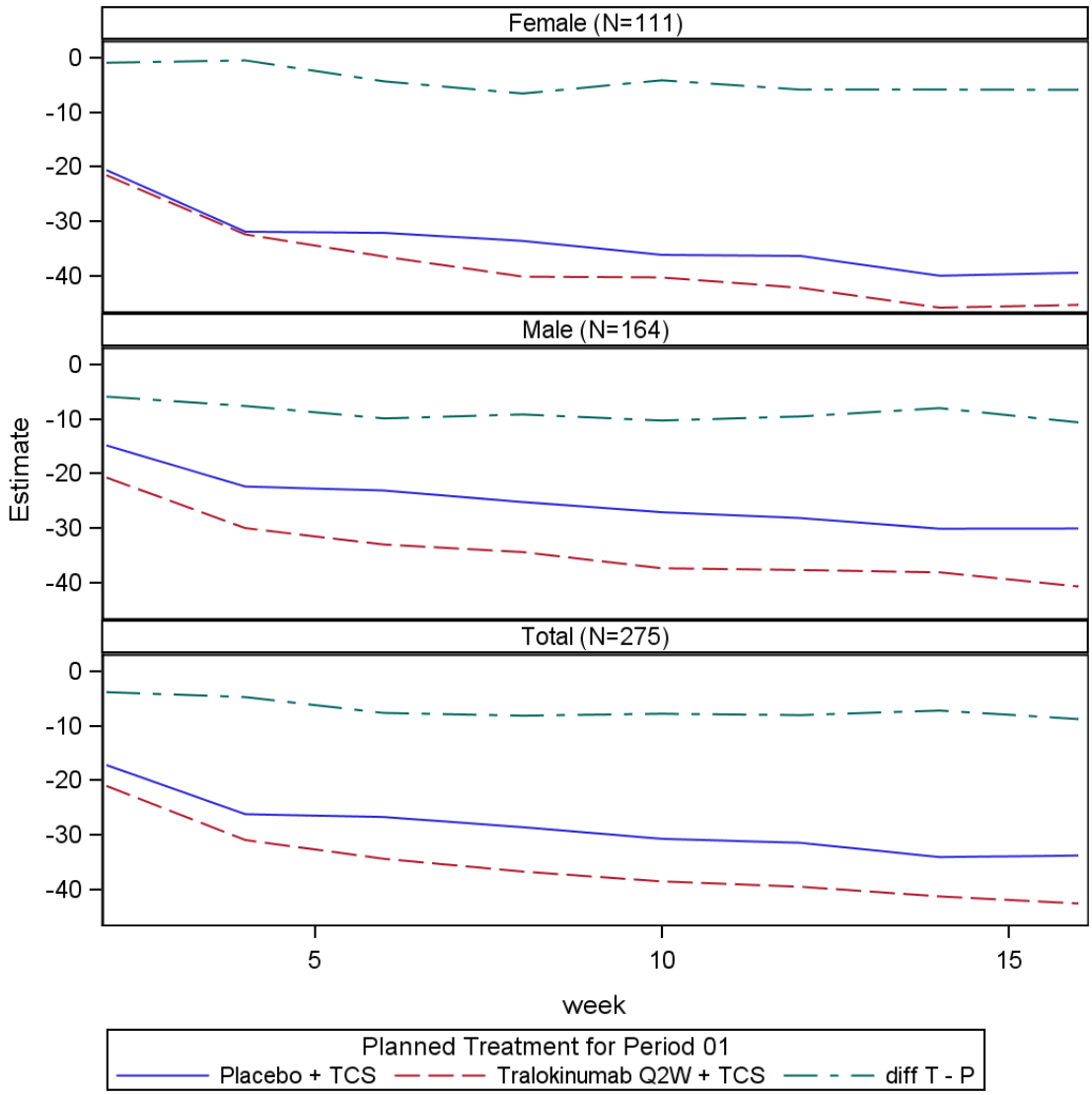
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1575
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.407.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	75	-31.3 (18.98)	-30.16 (1.93)	74	-38.2 (20.81)	-38.18 (1.95)	-8.02 (-13.4, -2.62) [-0.40 (-0.73, -0.08)]	0.004
Week 16	76	39.1 (17.10)		73	27.9 (17.02)			
Week 16 chg	76	-31.4 (18.33)	-30.13 (1.92)	73	-41.2 (18.55)	-40.77 (1.95)	-10.65 (-16.0, -5.25) [-0.58 (-0.91, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1575
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.407.4.2: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.4.409.4.1: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score											
Total											
Baseline	137	134	16.4 (6.33)			138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)				132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.15 (0.45)			132	-7.5 (5.92)	-7.56 (0.45)		-0.41 (-1.65, 0.84) 0.520 [-0.07 (-0.31, 0.17)]
Week 4		130	7.8 (6.27)				135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.32 (0.45)			135	-9.0 (6.32)	-9.14 (0.44)		-0.82 (-2.06, 0.42) 0.196 [-0.13 (-0.37, 0.12)]
Week 6		123	7.3 (6.07)				126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.65 (0.45)			126	-10.0 (6.75)	-9.87 (0.45)		-1.22 (-2.48, 0.03) 0.056 [-0.18 (-0.42, 0.07)]
Week 8		127	6.9 (5.70)				128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.97 (0.45)			128	-10.6 (6.29)	-10.39 (0.45)		-1.42 (-2.67, -0.17) 0.026 [-0.22 (-0.46, 0.03)]
Week 12		123	6.8 (5.89)				124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.30 (0.46)			124	-10.6 (5.77)	-10.58 (0.45)		-1.28 (-2.54, -0.02) 0.046 [-0.20 (-0.45, 0.05)]
Week 16		120	6.5 (5.63)				118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.46)			118	-11.0 (5.99)	-11.18 (0.46)		-1.50 (-2.77, -0.23) 0.021 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9345
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.409.4.1: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 17.2 (6.62)		57	57 17.1 (6.83)		
Week 2		51 9.2 (6.84)			57 9.0 (6.86)		
Week 2 chg		51 -8.0 (5.70)	-8.14 (0.76)		57 -8.1 (6.26)	-8.12 (0.73)	0.02 (-2.06, 2.10) 0.986 [0.00 (-0.37, 0.38)]
Week 4		52 7.9 (6.95)			57 7.2 (6.61)		
Week 4 chg		52 -9.4 (6.53)	-9.14 (0.76)		57 -9.9 (6.49)	-9.97 (0.73)	-0.83 (-2.91, 1.25) 0.433 [-0.13 (-0.50, 0.25)]
Week 6		48 6.7 (5.67)			55 6.3 (6.41)		
Week 6 chg		48 -10.8 (6.72)	-10.16 (0.77)		55 -10.9 (7.58)	-10.80 (0.73)	-0.63 (-2.73, 1.47) 0.553 [-0.09 (-0.48, 0.30)]
Week 8		49 6.4 (5.79)			53 5.7 (5.62)		
Week 8 chg		49 -10.8 (6.55)	-10.19 (0.77)		53 -11.7 (6.34)	-11.47 (0.74)	-1.28 (-3.38, 0.82) 0.232 [-0.20 (-0.59, 0.19)]
Week 12		48 6.4 (6.37)			51 5.2 (4.58)		
Week 12 chg		48 -11.0 (7.66)	-10.71 (0.77)		51 -11.7 (5.90)	-11.60 (0.74)	-0.89 (-3.01, 1.22) 0.406 [-0.13 (-0.53, 0.26)]
Week 16		45 6.0 (6.53)			47 4.6 (4.28)		
Week 16 chg		45 -11.4 (6.88)	-11.19 (0.78)		47 -12.3 (6.39)	-12.51 (0.75)	-1.33 (-3.47, 0.81) 0.223 [-0.20 (-0.61, 0.21)]

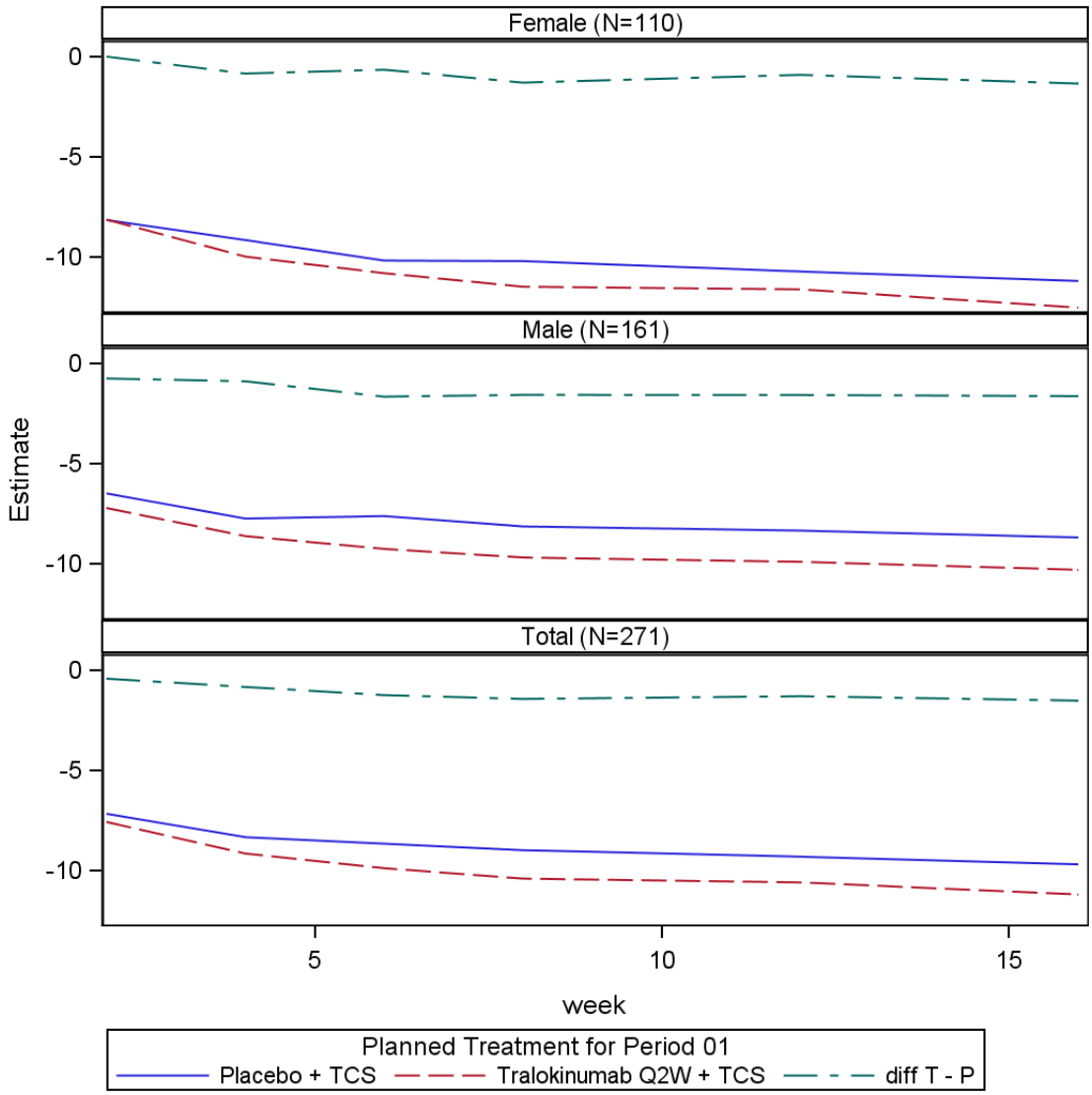
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9345
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.409.4.1: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	81 15.8 (6.11)		81	80 15.0 (6.22)		
Week 2		80 9.2 (6.27)			75 8.1 (5.61)		
Week 2 chg		80 -6.8 (5.73)	-6.47 (0.55)		75 -7.1 (5.65)	-7.20 (0.56)	-0.73 (-2.29, 0.82) 0.355 [-0.13 (-0.44, 0.19)]
Week 4		78 7.7 (5.83)			78 6.4 (5.50)		
Week 4 chg		78 -8.1 (6.76)	-7.73 (0.56)		78 -8.4 (6.16)	-8.60 (0.56)	-0.88 (-2.43, 0.68) 0.269 [-0.14 (-0.45, 0.18)]
Week 6		75 7.7 (6.32)			71 5.8 (5.30)		
Week 6 chg		75 -7.7 (7.34)	-7.60 (0.56)		71 -9.3 (6.00)	-9.24 (0.57)	-1.64 (-3.22, -0.06) 0.041 [-0.24 (-0.57, 0.08)]
Week 8		78 7.2 (5.67)			75 5.2 (4.75)		
Week 8 chg		78 -8.5 (6.91)	-8.12 (0.56)		75 -9.8 (6.17)	-9.67 (0.56)	-1.55 (-3.11, 0.01) 0.051 [-0.24 (-0.55, 0.08)]
Week 12		75 7.1 (5.60)			73 4.9 (3.42)		
Week 12 chg		75 -9.0 (6.92)	-8.33 (0.56)		73 -9.9 (5.59)	-9.89 (0.57)	-1.56 (-3.13, 0.02) 0.052 [-0.25 (-0.57, 0.08)]
Week 16		75 6.8 (5.04)			71 4.4 (3.62)		
Week 16 chg		75 -9.1 (6.23)	-8.67 (0.56)		71 -10.1 (5.60)	-10.29 (0.57)	-1.62 (-3.20, -0.04) 0.045 [-0.27 (-0.60, 0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9345
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.409.4.2: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.4.410.4.1: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total									
Total									
Baseline	137	134	20.9 (5.72)		138	135	21.3 (5.12)		
Week 2		130	15.1 (6.91)			130	13.5 (6.31)		
Week 2 chg		130	-5.9 (6.29)	-5.98 (0.55)		130	-7.7 (5.43)	-7.66 (0.54)	-1.69 (-3.20, -0.17) 0.029 [-0.29 (-0.53, -0.04)]
Week 4		130	13.8 (7.45)			133	11.6 (6.30)		
Week 4 chg		130	-7.1 (7.56)	-7.12 (0.55)		133	-9.7 (6.02)	-9.53 (0.54)	-2.40 (-3.92, -0.89) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123	13.5 (7.81)			124	10.9 (5.95)		
Week 6 chg		123	-7.2 (8.29)	-7.34 (0.55)		124	-10.6 (6.27)	-10.36 (0.55)	-3.02 (-4.56, -1.48) <.001 [-0.41 (-0.66, -0.16)]
Week 8		127	13.1 (7.02)			126	9.9 (5.79)		
Week 8 chg		127	-7.6 (7.95)	-7.73 (0.55)		126	-11.5 (6.10)	-11.20 (0.55)	-3.47 (-5.00, -1.94) <.001 [-0.49 (-0.74, -0.24)]
Week 12		123	13.0 (7.39)			122	9.2 (5.72)		
Week 12 chg		123	-8.0 (8.26)	-7.90 (0.55)		122	-12.4 (6.20)	-11.83 (0.55)	-3.93 (-5.47, -2.39) <.001 [-0.54 (-0.79, -0.28)]
Week 16		120	13.0 (7.69)			116	9.1 (5.58)		
Week 16 chg		120	-8.0 (8.09)	-8.05 (0.56)		116	-12.2 (6.39)	-11.87 (0.56)	-3.82 (-5.37, -2.27) <.001 [-0.52 (-0.78, -0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8893
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.410.4.1: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 21.2 (5.64)		57	55 21.7 (5.28)		
Week 2		50 14.8 (6.68)			55 14.0 (5.72)		
Week 2 chg		50 -6.6 (6.00)	-6.71 (0.87)		55 -7.7 (5.68)	-7.65 (0.85)	-0.94 (-3.34, 1.46) 0.441 [-0.16 (-0.54, 0.22)]
Week 4		52 13.6 (6.89)			55 11.6 (6.06)		
Week 4 chg		52 -7.6 (7.63)	-7.75 (0.87)		55 -10.1 (6.54)	-10.07 (0.85)	-2.31 (-4.71, 0.08) 0.058 [-0.33 (-0.71, 0.06)]
Week 6		48 12.9 (7.11)			53 11.6 (5.69)		
Week 6 chg		48 -8.3 (8.58)	-8.44 (0.89)		53 -10.4 (6.71)	-10.17 (0.85)	-1.73 (-4.16, 0.70) 0.162 [-0.23 (-0.62, 0.17)]
Week 8		49 12.9 (6.64)			51 10.1 (6.04)		
Week 8 chg		49 -8.2 (8.40)	-8.41 (0.88)		51 -12.0 (5.88)	-11.57 (0.86)	-3.16 (-5.60, -0.72) 0.011 [-0.44 (-0.83, -0.04)]
Week 12		48 12.9 (7.36)			49 9.2 (6.06)		
Week 12 chg		48 -8.4 (8.40)	-8.57 (0.89)		49 -13.1 (6.52)	-12.48 (0.87)	-3.91 (-6.36, -1.45) 0.002 [-0.52 (-0.93, -0.12)]
Week 16		45 12.5 (7.88)			45 8.8 (5.27)		
Week 16 chg		45 -8.9 (8.77)	-8.93 (0.90)		45 -13.2 (6.73)	-12.93 (0.89)	-3.99 (-6.49, -1.50) 0.002 [-0.51 (-0.93, -0.09)]

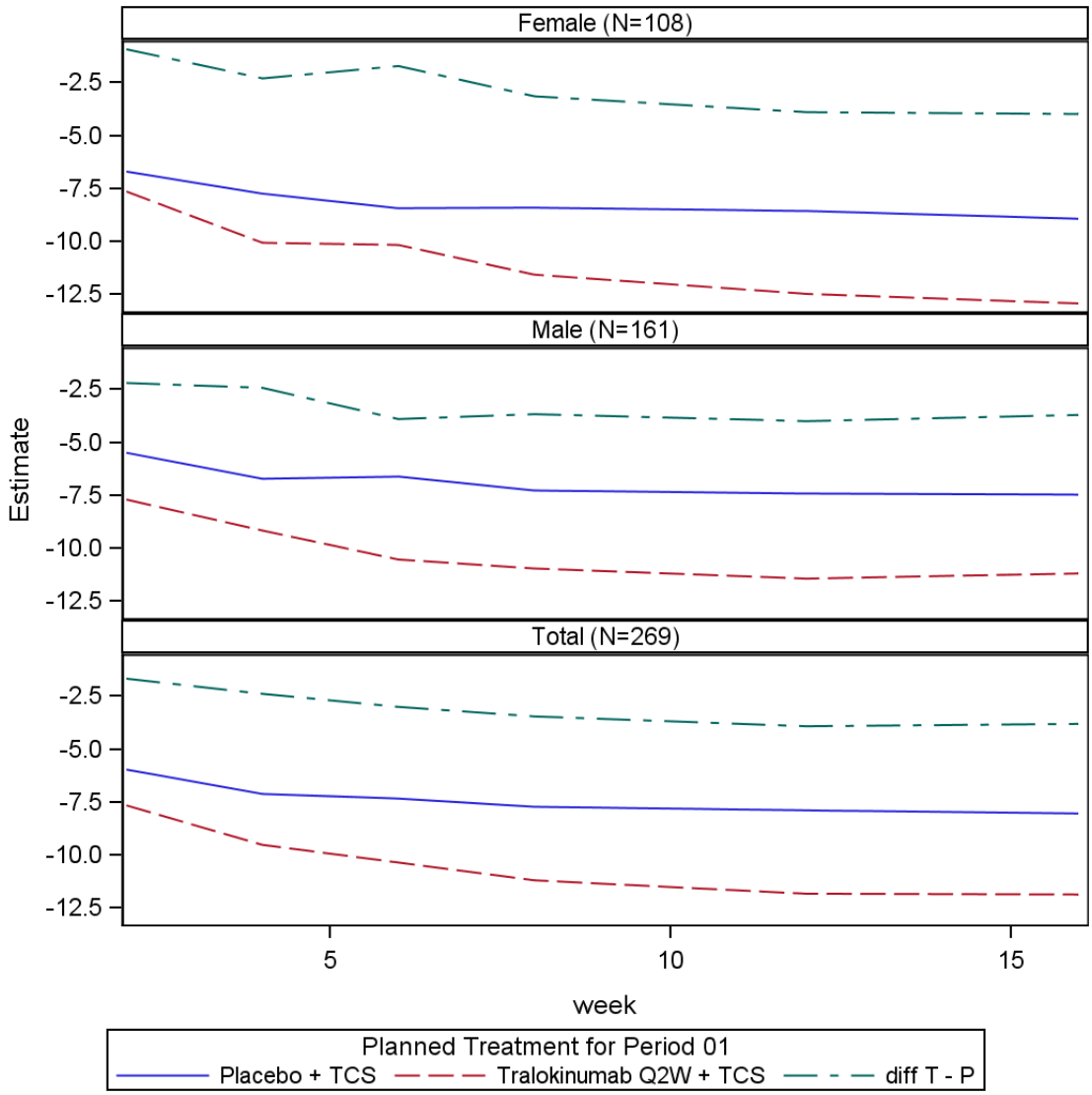
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8893
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.410.4.1: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	81 20.6 (5.80)		81	80 21.0 (5.02)		
Week 2		80 15.3 (7.09)			75 13.2 (6.73)		
Week 2 chg		80 -5.5 (6.46)	-5.50 (0.70)		75 -7.8 (5.27)	-7.71 (0.71)	-2.21 (-4.18, -0.24) 0.028 [-0.37 (-0.69, -0.06)]
Week 4		78 13.8 (7.85)			78 11.6 (6.51)		
Week 4 chg		78 -6.7 (7.54)	-6.73 (0.71)		78 -9.3 (5.65)	-9.17 (0.71)	-2.44 (-4.41, -0.47) 0.015 [-0.37 (-0.68, -0.05)]
Week 6		75 13.9 (8.24)			71 10.3 (6.13)		
Week 6 chg		75 -6.4 (8.07)	-6.63 (0.71)		71 -10.8 (5.96)	-10.54 (0.72)	-3.91 (-5.91, -1.91) <.001 [-0.55 (-0.88, -0.22)]
Week 8		78 13.3 (7.29)			75 9.8 (5.66)		
Week 8 chg		78 -7.2 (7.68)	-7.28 (0.71)		75 -11.2 (6.27)	-10.96 (0.72)	-3.68 (-5.66, -1.70) <.001 [-0.52 (-0.85, -0.20)]
Week 12		75 13.1 (7.46)			73 9.2 (5.52)		
Week 12 chg		75 -7.8 (8.22)	-7.43 (0.71)		73 -11.9 (5.97)	-11.44 (0.72)	-4.01 (-6.00, -2.02) <.001 [-0.56 (-0.89, -0.23)]
Week 16		75 13.2 (7.61)			71 9.2 (5.79)		
Week 16 chg		75 -7.5 (7.67)	-7.48 (0.71)		71 -11.5 (6.12)	-11.20 (0.72)	-3.72 (-5.71, -1.72) <.001 [-0.53 (-0.86, -0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8893
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.410.4.2: Total, Gender, change in POEM, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.4.414.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.60 (0.81)		138 -12.9 (10.72)	-13.33 (0.81)	-0.73 (-2.98, 1.53) 0.526 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.57 (0.81)		137 -18.8 (10.58)	-19.44 (0.81)	-1.86 (-4.13, 0.40) 0.106 [-0.17 (-0.40, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.53 (0.82)		134 -20.9 (11.93)	-21.51 (0.81)	-2.98 (-5.25, -0.71) 0.010 [-0.24 (-0.48, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.30 (0.82)		130 -22.5 (12.16)	-23.17 (0.82)	-3.88 (-6.15, -1.60) <.001 [-0.30 (-0.54, -0.05)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.61 (0.82)		130 -24.3 (11.55)	-25.02 (0.82)	-4.41 (-6.69, -2.13) <.001 [-0.34 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-21.10 (0.82)		128 -24.7 (12.40)	-25.22 (0.82)	-4.11 (-6.40, -1.83) <.001 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5243
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.414.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	11.2 (11.57)		127	7.0 (8.34)		
Week 14 chg	126	-22.8 (14.69)	-21.89 (0.82)	127	-25.1 (13.29)	-25.74 (0.82)	-3.85 (-6.14, -1.55) 0.001 [-0.27 (-0.52, -0.03)]
Week 16	124	10.5 (11.42)		123	6.4 (7.63)		
Week 16 chg	124	-23.8 (14.93)	-22.65 (0.83)	123	-25.9 (12.78)	-26.17 (0.83)	-3.52 (-5.82, -1.22) 0.003 [-0.25 (-0.50, -0.00)]
Week 18	116	10.7 (11.52)		115	5.9 (7.36)		
Week 18 chg	116	-23.6 (14.71)	-22.56 (0.84)	115	-26.4 (12.11)	-26.14 (0.84)	-3.58 (-5.91, -1.25) 0.003 [-0.27 (-0.52, -0.01)]
Week 20	107	10.6 (12.56)		117	5.5 (6.56)		
Week 20 chg	107	-24.1 (15.32)	-22.56 (0.85)	117	-26.9 (11.94)	-26.74 (0.84)	-4.18 (-6.53, -1.84) <.001 [-0.31 (-0.57, -0.04)]
Week 22	112	10.5 (11.17)		114	5.0 (5.93)		
Week 22 chg	112	-24.3 (14.63)	-22.40 (0.84)	114	-27.3 (12.17)	-27.13 (0.84)	-4.73 (-7.08, -2.39) <.001 [-0.35 (-0.61, -0.09)]
Week 24	112	9.9 (11.00)		117	5.3 (7.21)		
Week 24 chg	112	-24.9 (14.38)	-22.80 (0.84)	117	-27.0 (12.11)	-26.99 (0.84)	-4.19 (-6.53, -1.85) <.001 [-0.32 (-0.58, -0.06)]
Week 26	118	9.1 (10.14)		125	5.6 (7.90)		
Week 26 chg	118	-25.5 (13.74)	-23.71 (0.83)	125	-26.5 (12.83)	-27.01 (0.82)	-3.30 (-5.61, -0.99) 0.005 [-0.25 (-0.50, 0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5243
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.414.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 33.2 (14.65)		57	57 33.2 (12.33)		
Week 2		54 19.4 (14.30)			57 18.9 (13.09)		
Week 2 chg		54 -13.8 (10.42)	-13.87 (1.25)		57 -14.3 (11.11)	-14.44 (1.22)	-0.57 (-4.01, 2.87) 0.744 [-0.05 (-0.43, 0.32)]
Week 4		53 14.0 (12.45)			57 13.1 (10.67)		
Week 4 chg		53 -19.4 (12.85)	-19.49 (1.25)		57 -20.1 (11.53)	-20.34 (1.22)	-0.85 (-4.30, 2.60) 0.627 [-0.07 (-0.44, 0.30)]
Week 6		52 12.4 (11.99)			56 10.3 (8.63)		
Week 6 chg		52 -21.0 (12.46)	-21.26 (1.26)		56 -22.9 (11.93)	-23.09 (1.22)	-1.83 (-5.29, 1.63) 0.298 [-0.15 (-0.53, 0.23)]
Week 8		52 12.4 (12.69)			54 7.8 (6.31)		
Week 8 chg		52 -21.0 (14.93)	-21.29 (1.26)		54 -25.3 (12.72)	-25.48 (1.23)	-4.20 (-7.67, -0.73) 0.018 [-0.30 (-0.69, 0.08)]
Week 10		52 10.6 (11.25)			54 7.0 (6.92)		
Week 10 chg		52 -22.8 (14.62)	-23.08 (1.26)		54 -26.2 (12.43)	-26.24 (1.23)	-3.15 (-6.62, 0.32) 0.075 [-0.23 (-0.61, 0.15)]
Week 12		51 11.0 (11.52)			53 6.7 (6.69)		
Week 12 chg		51 -22.6 (15.95)	-22.96 (1.26)		53 -26.8 (12.05)	-26.64 (1.23)	-3.68 (-7.16, -0.20) 0.038 [-0.26 (-0.65, 0.13)]
Week 14		51 9.7 (11.64)			53 5.0 (5.79)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5243
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.414.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	51	-23.8 (16.37)	-24.18 (1.26)	53	-27.9 (12.60)	-28.09 (1.23)	-3.91 (-7.39, -0.43) 0.028 [-0.27 (-0.65, 0.12)]
Week 16	48	9.5 (12.99)		50	5.6 (7.06)		
Week 16 chg	48	-24.6 (17.73)	-24.34 (1.28)	50	-28.1 (13.46)	-27.47 (1.24)	-3.14 (-6.65, 0.38) 0.080 [-0.20 (-0.60, 0.20)]
Week 18	46	9.6 (12.02)		48	4.8 (6.99)		
Week 18 chg	46	-24.7 (16.46)	-24.64 (1.29)	48	-29.1 (12.88)	-27.57 (1.25)	-2.93 (-6.48, 0.61) 0.104 [-0.20 (-0.60, 0.21)]
Week 20	44	8.5 (12.21)		48	4.3 (5.75)		
Week 20 chg	44	-25.7 (16.87)	-25.61 (1.30)	48	-29.6 (12.18)	-28.09 (1.25)	-2.48 (-6.04, 1.08) 0.171 [-0.17 (-0.58, 0.24)]
Week 22	42	8.4 (10.41)		47	4.2 (5.00)		
Week 22 chg	42	-25.9 (16.03)	-24.94 (1.31)	47	-29.8 (13.01)	-28.19 (1.26)	-3.25 (-6.83, 0.33) 0.075 [-0.22 (-0.64, 0.19)]
Week 24	43	8.8 (10.75)		48	4.6 (5.97)		
Week 24 chg	43	-25.4 (16.78)	-24.39 (1.30)	48	-29.3 (12.57)	-28.02 (1.25)	-3.63 (-7.20, -0.07) 0.046 [-0.25 (-0.66, 0.17)]
Week 26	46	7.6 (9.25)		52	5.2 (6.08)		
Week 26 chg	46	-25.9 (16.27)	-25.35 (1.29)	52	-28.1 (12.63)	-27.53 (1.24)	-2.18 (-5.69, 1.34) 0.224 [-0.15 (-0.55, 0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5243
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.414.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 34.3 (12.71)		81	81 31.3 (10.94)		
Week 2		83 21.9 (13.69)			81 19.4 (12.59)		
Week 2 chg		83 -12.3 (11.64)	-11.69 (1.06)		81 -11.9 (10.39)	-12.63 (1.07)	-0.94 (-3.93, 2.04) 0.535 [-0.09 (-0.39, 0.22)]
Week 4		81 16.8 (12.63)			80 13.1 (10.22)		
Week 4 chg		81 -17.4 (11.30)	-16.33 (1.06)		80 -17.9 (9.83)	-18.79 (1.08)	-2.45 (-5.45, 0.55) 0.109 [-0.23 (-0.54, 0.08)]
Week 6		80 16.2 (12.51)			78 11.8 (10.36)		
Week 6 chg		80 -18.1 (12.67)	-16.72 (1.07)		78 -19.4 (11.79)	-20.42 (1.08)	-3.70 (-6.71, -0.69) 0.016 [-0.30 (-0.62, 0.01)]
Week 8		81 15.0 (12.72)			76 10.9 (9.58)		
Week 8 chg		81 -19.2 (13.15)	-18.05 (1.06)		76 -20.5 (11.42)	-21.51 (1.09)	-3.45 (-6.47, -0.44) 0.025 [-0.28 (-0.59, 0.03)]
Week 10		79 13.8 (11.84)			76 8.1 (7.79)		
Week 10 chg		79 -20.6 (13.48)	-19.00 (1.07)		76 -22.9 (10.74)	-24.19 (1.09)	-5.19 (-8.21, -2.16) <.001 [-0.42 (-0.74, -0.11)]
Week 12		77 12.7 (11.01)			75 8.3 (8.55)		
Week 12 chg		77 -21.9 (13.13)	-19.86 (1.08)		75 -23.2 (12.50)	-24.25 (1.09)	-4.39 (-7.42, -1.35) 0.005 [-0.34 (-0.66, -0.02)]
Week 14		75 12.3 (11.48)			74 8.4 (9.56)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5243
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

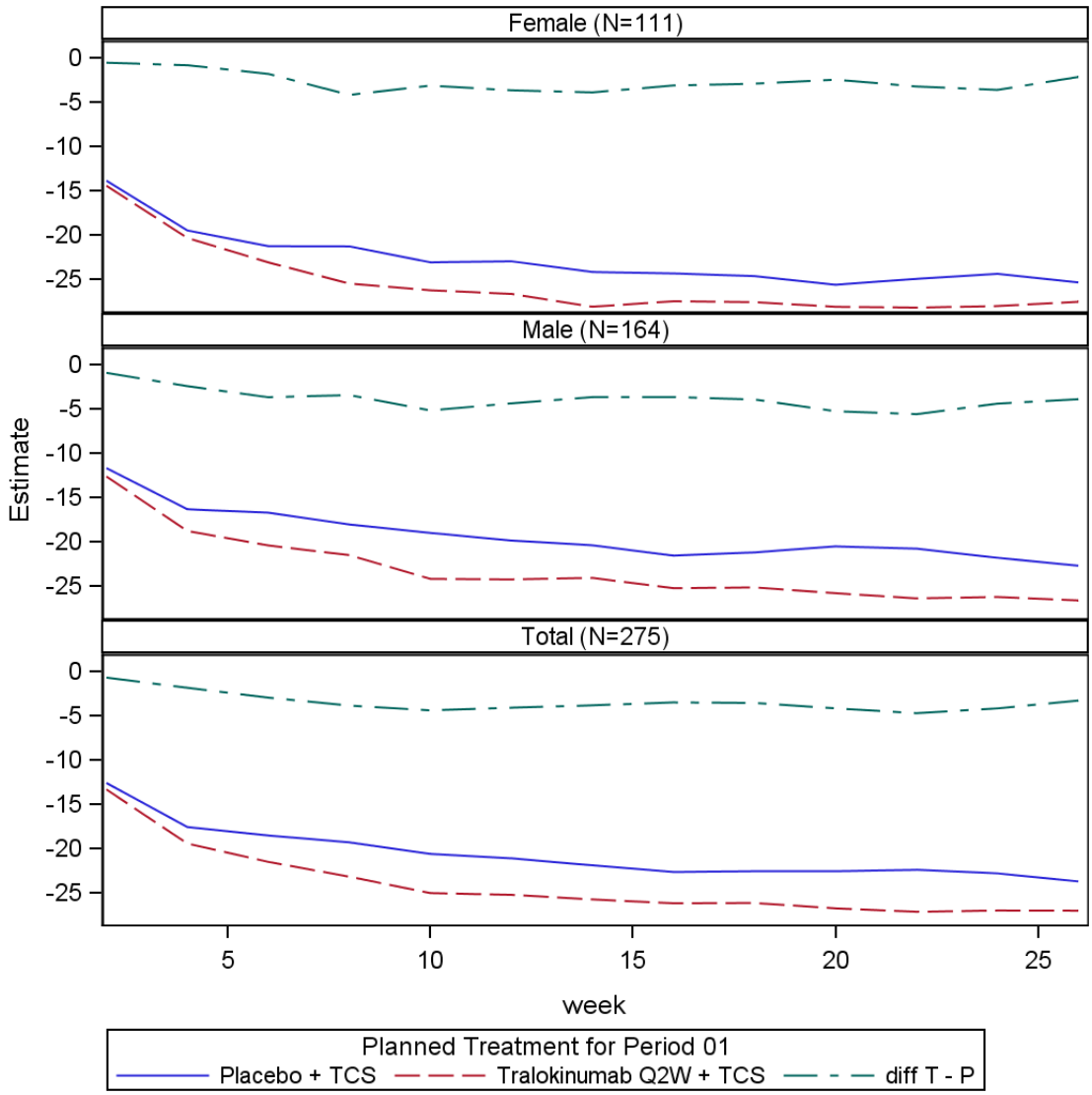
Table 1.4.414.4.1: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	75	-22.1 (13.51)	-20.39 (1.08)	74	-23.1 (13.48)	-24.08 (1.09)	-3.68 (-6.73, -0.64) 0.018 [-0.27 (-0.60, 0.05)]
Week 16	76	11.2 (10.34)		73	6.9 (8.01)		
Week 16 chg	76	-23.3 (12.96)	-21.56 (1.08)	73	-24.3 (12.14)	-25.24 (1.10)	-3.68 (-6.73, -0.63) 0.018 [-0.29 (-0.62, 0.03)]
Week 18	70	11.4 (11.20)		67	6.6 (7.57)		
Week 18 chg	70	-22.8 (13.52)	-21.20 (1.10)	67	-24.4 (11.22)	-25.15 (1.12)	-3.95 (-7.05, -0.85) 0.013 [-0.32 (-0.65, 0.02)]
Week 20	63	12.0 (12.70)		69	6.4 (6.99)		
Week 20 chg	63	-23.0 (14.17)	-20.52 (1.12)	69	-25.1 (11.50)	-25.80 (1.11)	-5.27 (-8.40, -2.15) <.001 [-0.41 (-0.76, -0.07)]
Week 22	70	11.8 (11.48)		67	5.6 (6.47)		
Week 22 chg	70	-23.4 (13.76)	-20.77 (1.10)	67	-25.6 (11.31)	-26.38 (1.12)	-5.61 (-8.71, -2.50) <.001 [-0.44 (-0.78, -0.11)]
Week 24	69	10.6 (11.18)		69	5.8 (7.97)		
Week 24 chg	69	-24.6 (12.79)	-21.81 (1.10)	69	-25.4 (11.60)	-26.22 (1.11)	-4.42 (-7.52, -1.32) 0.005 [-0.36 (-0.70, -0.03)]
Week 26	72	10.0 (10.64)		73	5.9 (9.01)		
Week 26 chg	72	-25.3 (11.97)	-22.70 (1.09)	73	-25.4 (12.93)	-26.62 (1.10)	-3.91 (-6.98, -0.85) 0.013 [-0.31 (-0.64, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5243
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 16:28 LP0162-Payer /p_mmrm3/t_t_gen_g14_46_w26.txt

Figure 1.4.414.4.2: Total, Gender, change in EASI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)			
Week 1		135 6.3 (1.69)			136 6.0 (1.78)			
Week 1 chg		135 -1.1 (1.34)	-1.12 (0.18)		136 -1.2 (1.31)	-1.22 (0.18)	-0.10 (-0.60, 0.40) [-0.07 (-0.31, 0.16)]	0.699
Week 2		134 5.8 (1.97)			132 5.4 (2.11)			
Week 2 chg		134 -1.7 (1.78)	-1.67 (0.18)		132 -1.9 (1.67)	-1.92 (0.18)	-0.24 (-0.74, 0.26) [-0.14 (-0.38, 0.10)]	0.338
Week 3		133 5.3 (2.17)			131 4.8 (2.08)			
Week 3 chg		133 -2.2 (2.12)	-2.11 (0.18)		131 -2.5 (1.84)	-2.53 (0.18)	-0.42 (-0.92, 0.08) [-0.21 (-0.46, 0.03)]	0.097
Week 4		130 5.1 (2.25)			133 4.4 (2.14)			
Week 4 chg		130 -2.4 (2.14)	-2.29 (0.18)		133 -2.8 (1.92)	-2.87 (0.18)	-0.58 (-1.08, -0.08) [-0.29 (-0.53, -0.04)]	0.023
Week 5		131 4.9 (2.37)			129 4.2 (2.15)			
Week 5 chg		131 -2.6 (2.26)	-2.53 (0.18)		129 -3.1 (1.92)	-3.16 (0.18)	-0.63 (-1.13, -0.13) [-0.30 (-0.54, -0.06)]	0.014
Week 6		130 4.8 (2.35)			129 4.2 (2.16)			
Week 6 chg		130 -2.7 (2.25)	-2.55 (0.18)		129 -3.1 (1.99)	-3.15 (0.18)	-0.61 (-1.11, -0.10) [-0.29 (-0.53, -0.04)]	0.018

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	4.7 (2.24)		128	4.0 (2.13)		
Week 7 chg	129	-2.8 (2.25)	-2.69 (0.18)	128	-3.3 (2.05)	-3.38 (0.18)	-0.69 (-1.19, -0.19) 0.007 [-0.32 (-0.57, -0.07)]
Week 8	127	4.7 (2.32)		125	3.7 (2.10)		
Week 8 chg	127	-2.8 (2.27)	-2.69 (0.18)	125	-3.7 (1.96)	-3.65 (0.18)	-0.96 (-1.46, -0.46) <.001 [-0.45 (-0.70, -0.20)]
Week 9	127	4.6 (2.37)		127	3.6 (2.10)		
Week 9 chg	127	-2.9 (2.32)	-2.76 (0.18)	127	-3.7 (2.03)	-3.71 (0.18)	-0.95 (-1.45, -0.45) <.001 [-0.44 (-0.69, -0.19)]
Week 10	125	4.5 (2.42)		122	3.6 (2.11)		
Week 10 chg	125	-2.9 (2.39)	-2.84 (0.18)	122	-3.7 (1.93)	-3.70 (0.18)	-0.87 (-1.37, -0.36) <.001 [-0.40 (-0.65, -0.15)]
Week 11	128	4.4 (2.41)		126	3.5 (2.15)		
Week 11 chg	128	-3.1 (2.40)	-3.03 (0.18)	126	-3.7 (1.97)	-3.76 (0.18)	-0.73 (-1.23, -0.23) 0.004 [-0.33 (-0.58, -0.09)]
Week 12	123	4.4 (2.36)		121	3.5 (2.08)		
Week 12 chg	123	-3.1 (2.41)	-2.99 (0.18)	121	-3.8 (2.06)	-3.82 (0.18)	-0.83 (-1.33, -0.32) 0.001 [-0.37 (-0.62, -0.12)]
Week 13	116	4.3 (2.38)		120	3.3 (2.06)		
Week 13 chg	116	-3.3 (2.35)	-3.05 (0.18)	120	-4.0 (2.09)	-3.92 (0.18)	-0.87 (-1.38, -0.37) <.001 [-0.39 (-0.65, -0.14)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.11 (0.18)	123	-3.9 (2.12)	-3.85 (0.18)	-0.74 (-1.25, -0.24) [-0.33 (-0.59, -0.08)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.17 (0.18)	123	-4.0 (2.15)	-3.93 (0.18)	-0.76 (-1.26, -0.25) [-0.34 (-0.59, -0.09)]	0.003
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.09 (0.18)	122	-3.9 (2.06)	-3.95 (0.18)	-0.85 (-1.36, -0.35) [-0.39 (-0.64, -0.13)]	<.001
Week 17	121	4.3 (2.46)		121	3.4 (2.13)			
Week 17 chg	121	-3.2 (2.49)	-3.09 (0.18)	121	-3.9 (2.04)	-3.93 (0.18)	-0.84 (-1.35, -0.34) [-0.37 (-0.63, -0.12)]	0.001
Week 18	120	4.4 (2.51)		123	3.3 (2.12)			
Week 18 chg	120	-3.2 (2.46)	-3.04 (0.18)	123	-4.0 (2.11)	-3.96 (0.18)	-0.93 (-1.43, -0.42) [-0.40 (-0.66, -0.15)]	<.001
Week 19	119	4.3 (2.65)		117	3.1 (2.11)			
Week 19 chg	119	-3.3 (2.55)	-3.09 (0.18)	117	-4.2 (2.19)	-4.16 (0.18)	-1.07 (-1.58, -0.57) [-0.45 (-0.71, -0.19)]	<.001
Week 20	120	4.3 (2.68)		118	3.0 (2.02)			
Week 20 chg	120	-3.3 (2.61)	-3.08 (0.18)	118	-4.2 (2.13)	-4.13 (0.18)	-1.05 (-1.56, -0.54) [-0.44 (-0.70, -0.18)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21	118	4.2 (2.59)		115	3.0 (1.94)		
Week 21 chg	118	-3.4 (2.59)	-3.21 (0.18)	115	-4.3 (2.07)	-4.22 (0.18)	-1.01 (-1.52, -0.50) <.001 [-0.43 (-0.69, -0.17)]
Week 22	120	4.2 (2.64)		116	3.0 (1.90)		
Week 22 chg	120	-3.4 (2.64)	-3.23 (0.18)	116	-4.2 (2.06)	-4.23 (0.18)	-1.01 (-1.51, -0.50) <.001 [-0.42 (-0.68, -0.17)]
Week 23	120	4.1 (2.62)		114	3.0 (1.94)		
Week 23 chg	120	-3.5 (2.58)	-3.28 (0.18)	114	-4.3 (2.15)	-4.23 (0.18)	-0.95 (-1.46, -0.44) <.001 [-0.40 (-0.66, -0.14)]
Week 24	120	4.1 (2.52)		112	2.9 (1.92)		
Week 24 chg	120	-3.4 (2.53)	-3.26 (0.18)	112	-4.3 (2.13)	-4.28 (0.18)	-1.02 (-1.53, -0.51) <.001 [-0.43 (-0.69, -0.17)]
Week 25	114	3.8 (2.46)		115	2.9 (1.90)		
Week 25 chg	114	-3.8 (2.50)	-3.46 (0.18)	115	-4.3 (2.08)	-4.34 (0.18)	-0.88 (-1.39, -0.37) <.001 [-0.38 (-0.65, -0.12)]
Week 26	112	3.9 (2.49)		118	3.0 (1.91)		
Week 26 chg	112	-3.6 (2.56)	-3.32 (0.18)	118	-4.3 (2.11)	-4.28 (0.18)	-0.96 (-1.47, -0.45) <.001 [-0.41 (-0.67, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 7.7 (1.40)		57	57 7.6 (1.42)		
Week 1		53 6.4 (1.87)			56 6.4 (1.63)		
Week 1 chg		53 -1.3 (1.42)	-1.30 (0.31)		56 -1.2 (1.34)	-1.18 (0.30)	0.12 (-0.75, 0.98) 0.785 [0.09 (-0.29, 0.46)]
Week 2		53 5.8 (2.11)			57 5.9 (2.03)		
Week 2 chg		53 -1.8 (1.75)	-1.82 (0.31)		57 -1.7 (1.64)	-1.73 (0.30)	0.09 (-0.78, 0.95) 0.842 [0.05 (-0.32, 0.43)]
Week 3		52 5.3 (2.38)			57 5.1 (2.09)		
Week 3 chg		52 -2.4 (2.25)	-2.36 (0.32)		57 -2.5 (1.91)	-2.53 (0.30)	-0.17 (-1.03, 0.70) 0.703 [-0.08 (-0.46, 0.30)]
Week 4		52 4.9 (2.54)			57 4.7 (2.29)		
Week 4 chg		52 -2.8 (2.36)	-2.72 (0.32)		57 -2.9 (2.14)	-2.90 (0.30)	-0.19 (-1.05, 0.68) 0.671 [-0.08 (-0.46, 0.29)]
Week 5		52 4.7 (2.68)			55 4.3 (2.22)		
Week 5 chg		52 -2.9 (2.49)	-2.88 (0.32)		55 -3.3 (2.11)	-3.42 (0.30)	-0.55 (-1.41, 0.32) 0.214 [-0.24 (-0.62, 0.14)]
Week 6		51 4.7 (2.59)			55 4.4 (2.22)		
Week 6 chg		51 -3.1 (2.48)	-2.96 (0.32)		55 -3.2 (2.23)	-3.31 (0.30)	-0.35 (-1.22, 0.52) 0.426 [-0.15 (-0.53, 0.23)]
Week 7		51 4.7 (2.41)			54 4.2 (2.25)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	51	-3.1 (2.40)	-2.96 (0.32)	54	-3.5 (2.30)	-3.52 (0.31)	-0.56 (-1.43, 0.31) [-0.24 (-0.62, 0.14)]	0.203
Week 8	50	4.6 (2.45)		54	3.8 (2.19)			
Week 8 chg	50	-3.2 (2.45)	-3.05 (0.32)	54	-3.9 (2.19)	-3.93 (0.31)	-0.88 (-1.75, -0.01) [-0.38 (-0.77, 0.01)]	0.048
Week 9	50	4.6 (2.56)		54	3.7 (2.23)			
Week 9 chg	50	-3.1 (2.51)	-3.06 (0.32)	54	-4.0 (2.25)	-4.00 (0.31)	-0.94 (-1.81, -0.07) [-0.40 (-0.78, -0.01)]	0.034
Week 10	49	4.4 (2.55)		53	3.8 (2.17)			
Week 10 chg	49	-3.3 (2.53)	-3.21 (0.32)	53	-3.9 (2.15)	-3.95 (0.31)	-0.73 (-1.61, 0.14) [-0.31 (-0.70, 0.08)]	0.098
Week 11	50	4.2 (2.54)		53	3.7 (2.29)			
Week 11 chg	50	-3.5 (2.51)	-3.45 (0.32)	53	-3.9 (2.25)	-4.01 (0.31)	-0.56 (-1.43, 0.31) [-0.24 (-0.62, 0.15)]	0.203
Week 12	48	4.1 (2.69)		53	3.7 (2.22)			
Week 12 chg	48	-3.6 (2.71)	-3.52 (0.32)	53	-4.0 (2.37)	-4.05 (0.31)	-0.53 (-1.40, 0.34) [-0.21 (-0.60, 0.18)]	0.232
Week 13	48	3.9 (2.56)		51	3.3 (2.33)			
Week 13 chg	48	-3.8 (2.61)	-3.68 (0.32)	51	-4.3 (2.48)	-4.25 (0.31)	-0.58 (-1.45, 0.30) [-0.23 (-0.62, 0.17)]	0.196
Week 14	49	3.8 (2.55)		53	3.5 (2.41)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	49	-3.9 (2.59)	-3.77 (0.32)	53	-4.1 (2.57)	-4.14 (0.31)	-0.37 (-1.24, 0.50) [-0.14 (-0.53, 0.24)]	0.401
Week 15	49	4.0 (2.51)		53	3.4 (2.48)			
Week 15 chg	49	-3.8 (2.54)	-3.68 (0.32)	53	-4.3 (2.64)	-4.27 (0.31)	-0.59 (-1.46, 0.28) [-0.23 (-0.62, 0.16)]	0.182
Week 16	50	3.8 (2.42)		52	3.4 (2.39)			
Week 16 chg	50	-3.9 (2.55)	-3.72 (0.32)	52	-4.2 (2.45)	-4.27 (0.31)	-0.56 (-1.43, 0.32) [-0.22 (-0.61, 0.17)]	0.209
Week 17	50	3.9 (2.64)		51	3.6 (2.52)			
Week 17 chg	50	-3.9 (2.75)	-3.79 (0.32)	51	-4.0 (2.55)	-4.12 (0.31)	-0.32 (-1.20, 0.55) [-0.12 (-0.51, 0.27)]	0.464
Week 18	48	4.1 (2.80)		53	3.5 (2.50)			
Week 18 chg	48	-3.7 (2.77)	-3.65 (0.32)	53	-4.2 (2.57)	-4.21 (0.31)	-0.56 (-1.43, 0.32) [-0.21 (-0.60, 0.18)]	0.210
Week 19	48	3.9 (2.83)		51	3.3 (2.62)			
Week 19 chg	48	-3.9 (2.77)	-3.81 (0.32)	51	-4.3 (2.72)	-4.30 (0.31)	-0.50 (-1.37, 0.38) [-0.18 (-0.58, 0.21)]	0.265
Week 20	48	3.7 (2.78)		48	3.3 (2.50)			
Week 20 chg	48	-4.1 (2.70)	-3.98 (0.32)	48	-4.3 (2.71)	-4.23 (0.31)	-0.26 (-1.13, 0.62) [-0.09 (-0.49, 0.31)]	0.566
Week 21	47	3.5 (2.52)		47	3.0 (2.36)			

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Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	47	-4.2 (2.56)	-4.10 (0.32)	47	-4.5 (2.52)	-4.48 (0.31)	-0.38 (-1.26, 0.50) 0.393 [-0.15 (-0.56, 0.25)]
Week 22	47	3.5 (2.68)		47	3.1 (2.21)		
Week 22 chg	47	-4.2 (2.78)	-4.07 (0.32)	47	-4.5 (2.44)	-4.49 (0.31)	-0.42 (-1.30, 0.46) 0.352 [-0.16 (-0.56, 0.25)]
Week 23	48	3.4 (2.59)		48	3.1 (2.26)		
Week 23 chg	48	-4.3 (2.72)	-4.12 (0.32)	48	-4.5 (2.55)	-4.46 (0.31)	-0.34 (-1.22, 0.54) 0.444 [-0.13 (-0.53, 0.27)]
Week 24	47	3.5 (2.56)		48	3.1 (2.24)		
Week 24 chg	47	-4.2 (2.75)	-4.09 (0.32)	48	-4.5 (2.55)	-4.52 (0.31)	-0.43 (-1.31, 0.45) 0.333 [-0.16 (-0.57, 0.24)]
Week 25	47	3.3 (2.58)		51	3.0 (2.26)		
Week 25 chg	47	-4.4 (2.74)	-4.18 (0.32)	51	-4.6 (2.54)	-4.59 (0.31)	-0.41 (-1.29, 0.46) 0.355 [-0.16 (-0.55, 0.24)]
Week 26	45	3.4 (2.53)		51	3.1 (2.27)		
Week 26 chg	45	-4.3 (2.83)	-4.00 (0.32)	51	-4.5 (2.54)	-4.51 (0.31)	-0.51 (-1.39, 0.37) 0.254 [-0.19 (-0.59, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 7.3 (1.34)		81	80 7.0 (1.43)		
Week 1		82 6.3 (1.58)			80 5.8 (1.85)		
Week 1 chg		82 -1.0 (1.28)	-1.00 (0.21)		80 -1.2 (1.30)	-1.27 (0.21)	-0.27 (-0.87, 0.32) 0.367 [-0.21 (-0.52, 0.10)]
Week 2		81 5.7 (1.89)			75 5.0 (2.09)		
Week 2 chg		81 -1.6 (1.80)	-1.55 (0.21)		75 -2.0 (1.69)	-2.09 (0.22)	-0.55 (-1.14, 0.05) 0.073 [-0.31 (-0.63, 0.00)]
Week 3		81 5.4 (2.03)			74 4.5 (2.04)		
Week 3 chg		81 -2.0 (2.02)	-1.92 (0.21)		74 -2.5 (1.79)	-2.57 (0.22)	-0.64 (-1.24, -0.04) 0.036 [-0.34 (-0.65, -0.02)]
Week 4		78 5.3 (2.04)			76 4.2 (2.01)		
Week 4 chg		78 -2.1 (1.95)	-1.99 (0.21)		76 -2.8 (1.75)	-2.87 (0.22)	-0.88 (-1.48, -0.28) 0.004 [-0.47 (-0.79, -0.15)]
Week 5		79 5.0 (2.15)			74 4.1 (2.11)		
Week 5 chg		79 -2.4 (2.09)	-2.29 (0.21)		74 -2.9 (1.77)	-2.98 (0.22)	-0.69 (-1.29, -0.09) 0.024 [-0.36 (-0.68, -0.04)]
Week 6		79 4.9 (2.18)			74 4.0 (2.11)		
Week 6 chg		79 -2.4 (2.06)	-2.27 (0.21)		74 -3.0 (1.79)	-3.04 (0.22)	-0.77 (-1.37, -0.17) 0.012 [-0.40 (-0.72, -0.08)]
Week 7		78 4.7 (2.14)			74 3.8 (2.04)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	78	-2.7 (2.14)	-2.51 (0.21)	74	-3.2 (1.86)	-3.29 (0.22)	-0.78 (-1.38, -0.18) 0.011 [-0.39 (-0.71, -0.07)]
Week 8	77	4.7 (2.25)		71	3.6 (2.04)		
Week 8 chg	77	-2.6 (2.13)	-2.45 (0.21)	71	-3.5 (1.75)	-3.45 (0.22)	-1.00 (-1.60, -0.40) 0.001 [-0.51 (-0.84, -0.18)]
Week 9	77	4.7 (2.26)		73	3.6 (2.02)		
Week 9 chg	77	-2.7 (2.20)	-2.55 (0.21)	73	-3.5 (1.84)	-3.51 (0.22)	-0.96 (-1.56, -0.35) 0.002 [-0.47 (-0.80, -0.15)]
Week 10	76	4.7 (2.34)		69	3.5 (2.07)		
Week 10 chg	76	-2.7 (2.27)	-2.58 (0.21)	69	-3.5 (1.75)	-3.53 (0.22)	-0.95 (-1.55, -0.35) 0.002 [-0.47 (-0.80, -0.14)]
Week 11	78	4.5 (2.33)		73	3.4 (2.05)		
Week 11 chg	78	-2.9 (2.30)	-2.74 (0.21)	73	-3.6 (1.75)	-3.58 (0.22)	-0.84 (-1.44, -0.24) 0.006 [-0.41 (-0.73, -0.09)]
Week 12	75	4.5 (2.13)		68	3.4 (1.97)		
Week 12 chg	75	-2.8 (2.16)	-2.64 (0.21)	68	-3.6 (1.78)	-3.66 (0.22)	-1.02 (-1.63, -0.42) 0.001 [-0.51 (-0.85, -0.18)]
Week 13	68	4.6 (2.22)		69	3.3 (1.86)		
Week 13 chg	68	-2.9 (2.09)	-2.62 (0.22)	69	-3.7 (1.72)	-3.67 (0.22)	-1.05 (-1.66, -0.44) <.001 [-0.55 (-0.89, -0.21)]
Week 14	74	4.5 (2.24)		70	3.3 (1.90)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	74	-2.9 (2.07)	-2.68 (0.21)	70	-3.7 (1.70)	-3.64 (0.22)	-0.96 (-1.57, -0.36) [-0.51 (-0.84, -0.18)]	0.002
Week 15	74	4.4 (2.17)		70	3.3 (1.79)			
Week 15 chg	74	-3.0 (2.13)	-2.83 (0.21)	70	-3.7 (1.66)	-3.69 (0.22)	-0.86 (-1.46, -0.25) [-0.45 (-0.78, -0.12)]	0.006
Week 16	71	4.5 (2.16)		70	3.3 (1.78)			
Week 16 chg	71	-2.9 (2.11)	-2.67 (0.21)	70	-3.7 (1.71)	-3.71 (0.22)	-1.05 (-1.65, -0.44) [-0.54 (-0.88, -0.21)]	<.001
Week 17	71	4.6 (2.30)		70	3.2 (1.78)			
Week 17 chg	71	-2.8 (2.20)	-2.61 (0.21)	70	-3.8 (1.59)	-3.80 (0.22)	-1.19 (-1.80, -0.59) [-0.62 (-0.96, -0.28)]	<.001
Week 18	72	4.6 (2.29)		70	3.2 (1.79)			
Week 18 chg	72	-2.8 (2.19)	-2.62 (0.21)	70	-3.8 (1.67)	-3.79 (0.22)	-1.18 (-1.78, -0.57) [-0.60 (-0.94, -0.27)]	<.001
Week 19	71	4.6 (2.49)		66	2.8 (1.60)			
Week 19 chg	71	-2.8 (2.30)	-2.59 (0.22)	66	-4.1 (1.69)	-4.07 (0.22)	-1.48 (-2.09, -0.87) [-0.73 (-1.07, -0.38)]	<.001
Week 20	72	4.8 (2.54)		70	2.9 (1.61)			
Week 20 chg	72	-2.7 (2.42)	-2.47 (0.21)	70	-4.1 (1.63)	-4.06 (0.22)	-1.59 (-2.20, -0.99) [-0.77 (-1.11, -0.43)]	<.001
Week 21	71	4.6 (2.56)		68	3.0 (1.59)			

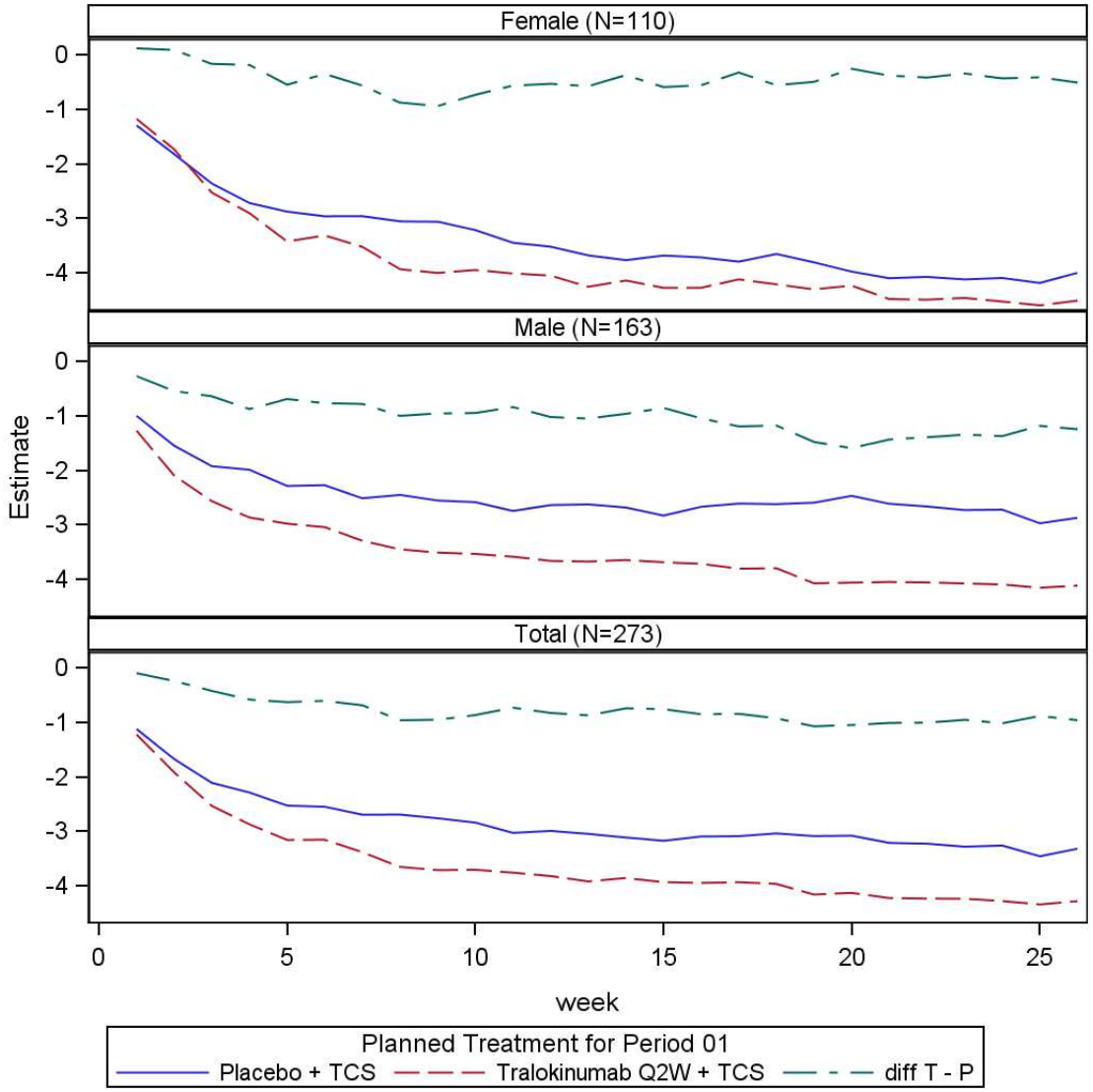
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.416.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	71	-2.8 (2.47)	-2.61 (0.21)	68	-4.1 (1.69)	-4.05 (0.22)	-1.43 (-2.04, -0.83) <.001 [-0.67 (-1.02, -0.33)]
Week 22	73	4.6 (2.54)		69	2.9 (1.67)		
Week 22 chg	73	-2.9 (2.43)	-2.66 (0.21)	69	-4.1 (1.77)	-4.06 (0.22)	-1.39 (-2.00, -0.79) <.001 [-0.65 (-0.99, -0.32)]
Week 23	72	4.5 (2.55)		66	2.9 (1.67)		
Week 23 chg	72	-2.9 (2.35)	-2.73 (0.21)	66	-4.1 (1.80)	-4.07 (0.22)	-1.35 (-1.96, -0.74) <.001 [-0.64 (-0.98, -0.30)]
Week 24	73	4.5 (2.42)		64	2.8 (1.66)		
Week 24 chg	73	-2.9 (2.26)	-2.72 (0.21)	64	-4.1 (1.75)	-4.09 (0.22)	-1.37 (-1.98, -0.76) <.001 [-0.67 (-1.02, -0.33)]
Week 25	67	4.1 (2.34)		64	2.8 (1.56)		
Week 25 chg	67	-3.3 (2.23)	-2.97 (0.22)	64	-4.1 (1.63)	-4.15 (0.22)	-1.18 (-1.80, -0.57) <.001 [-0.60 (-0.95, -0.25)]
Week 26	67	4.3 (2.41)		67	2.9 (1.59)		
Week 26 chg	67	-3.1 (2.27)	-2.87 (0.22)	67	-4.1 (1.72)	-4.11 (0.22)	-1.24 (-1.86, -0.63) <.001 [-0.62 (-0.97, -0.27)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.416.4.2: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 1		135 5.8 (2.01)			136 5.2 (2.21)		
Week 1 chg		135 -1.1 (1.50)	-1.05 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.10 (-0.61, 0.42) 0.715 [-0.07 (-0.30, 0.17)]
Week 2		134 5.2 (2.29)			132 4.5 (2.45)		
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.19)	-0.18 (-0.70, 0.34) 0.502 [-0.09 (-0.33, 0.15)]
Week 3		133 4.7 (2.36)			131 3.9 (2.35)		
Week 3 chg		133 -2.2 (2.17)	-2.12 (0.19)		131 -2.4 (2.01)	-2.49 (0.19)	-0.37 (-0.89, 0.15) 0.165 [-0.18 (-0.42, 0.07)]
Week 4		130 4.5 (2.48)			133 3.6 (2.39)		
Week 4 chg		130 -2.4 (2.23)	-2.25 (0.19)		133 -2.7 (2.06)	-2.79 (0.19)	-0.54 (-1.06, -0.02) 0.041 [-0.25 (-0.50, -0.01)]
Week 5		131 4.2 (2.55)			129 3.3 (2.42)		
Week 5 chg		131 -2.7 (2.37)	-2.54 (0.19)		129 -3.0 (2.16)	-3.13 (0.19)	-0.59 (-1.11, -0.07) 0.027 [-0.26 (-0.50, -0.01)]
Week 6		130 4.2 (2.52)			129 3.3 (2.42)		
Week 6 chg		130 -2.7 (2.36)	-2.50 (0.19)		129 -3.1 (2.24)	-3.21 (0.19)	-0.71 (-1.23, -0.19) 0.008 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	3.9 (2.43)		128	3.1 (2.37)			
Week 7 chg	129	-3.0 (2.38)	-2.77 (0.19)	128	-3.3 (2.28)	-3.41 (0.19)	-0.64 (-1.16, -0.12) [-0.27 (-0.52, -0.03)]	0.016
Week 8	127	3.9 (2.46)		125	2.8 (2.29)			
Week 8 chg	127	-3.0 (2.32)	-2.75 (0.19)	125	-3.6 (2.26)	-3.65 (0.19)	-0.90 (-1.42, -0.38) [-0.39 (-0.64, -0.14)]	<.001
Week 9	127	3.8 (2.49)		127	2.6 (2.22)			
Week 9 chg	127	-3.1 (2.33)	-2.89 (0.19)	127	-3.7 (2.23)	-3.84 (0.19)	-0.95 (-1.47, -0.43) [-0.41 (-0.66, -0.17)]	<.001
Week 10	125	3.7 (2.54)		122	2.7 (2.29)			
Week 10 chg	125	-3.2 (2.40)	-3.00 (0.19)	122	-3.7 (2.29)	-3.82 (0.19)	-0.82 (-1.34, -0.30) [-0.35 (-0.60, -0.10)]	0.002
Week 11	128	3.6 (2.46)		126	2.6 (2.22)			
Week 11 chg	128	-3.3 (2.40)	-3.11 (0.19)	126	-3.8 (2.26)	-3.90 (0.19)	-0.78 (-1.31, -0.26) [-0.34 (-0.58, -0.09)]	0.003
Week 12	123	3.5 (2.44)		121	2.5 (2.21)			
Week 12 chg	123	-3.4 (2.45)	-3.14 (0.19)	121	-3.8 (2.38)	-4.00 (0.19)	-0.86 (-1.38, -0.33) [-0.36 (-0.61, -0.10)]	0.001
Week 13	116	3.4 (2.40)		120	2.3 (2.13)			
Week 13 chg	116	-3.6 (2.32)	-3.27 (0.19)	120	-3.9 (2.26)	-4.04 (0.19)	-0.77 (-1.30, -0.25) [-0.34 (-0.59, -0.08)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	123	3.3 (2.42)		123	2.4 (2.18)		
Week 14 chg	123	-3.5 (2.33)	-3.34 (0.19)	123	-3.9 (2.27)	-4.04 (0.19)	-0.70 (-1.22, -0.18) 0.009 [-0.30 (-0.56, -0.05)]
Week 15	123	3.3 (2.47)		123	2.4 (2.18)		
Week 15 chg	123	-3.7 (2.35)	-3.43 (0.19)	123	-3.9 (2.35)	-4.08 (0.19)	-0.65 (-1.17, -0.12) 0.015 [-0.28 (-0.53, -0.02)]
Week 16	121	3.2 (2.40)		122	2.5 (2.17)		
Week 16 chg	121	-3.7 (2.28)	-3.40 (0.19)	122	-3.9 (2.32)	-4.07 (0.19)	-0.67 (-1.20, -0.15) 0.012 [-0.29 (-0.55, -0.04)]
Week 17	121	3.4 (2.55)		121	2.4 (2.30)		
Week 17 chg	121	-3.6 (2.46)	-3.34 (0.19)	121	-4.0 (2.36)	-4.10 (0.19)	-0.76 (-1.28, -0.23) 0.005 [-0.31 (-0.57, -0.06)]
Week 18	120	3.4 (2.65)		123	2.3 (2.24)		
Week 18 chg	120	-3.6 (2.51)	-3.35 (0.19)	123	-4.0 (2.40)	-4.15 (0.19)	-0.79 (-1.31, -0.27) 0.003 [-0.32 (-0.58, -0.07)]
Week 19	119	3.3 (2.75)		117	2.2 (2.22)		
Week 19 chg	119	-3.7 (2.57)	-3.42 (0.19)	117	-4.1 (2.46)	-4.23 (0.19)	-0.81 (-1.33, -0.28) 0.003 [-0.32 (-0.58, -0.06)]
Week 20	120	3.4 (2.78)		118	2.2 (2.12)		
Week 20 chg	120	-3.6 (2.63)	-3.32 (0.19)	118	-4.1 (2.42)	-4.18 (0.19)	-0.87 (-1.39, -0.34) 0.001 [-0.34 (-0.60, -0.09)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21	118	3.2 (2.67)		115	2.1 (2.04)		
Week 21 chg	118	-3.8 (2.62)	-3.49 (0.19)	115	-4.2 (2.37)	-4.32 (0.19)	-0.83 (-1.36, -0.30) 0.002 [-0.33 (-0.59, -0.07)]
Week 22	120	3.3 (2.72)		116	2.0 (1.98)		
Week 22 chg	120	-3.7 (2.65)	-3.37 (0.19)	116	-4.3 (2.35)	-4.38 (0.19)	-1.00 (-1.53, -0.48) <.001 [-0.40 (-0.66, -0.14)]
Week 23	120	3.2 (2.64)		114	2.0 (2.02)		
Week 23 chg	120	-3.7 (2.56)	-3.45 (0.19)	114	-4.2 (2.44)	-4.35 (0.19)	-0.90 (-1.43, -0.37) <.001 [-0.36 (-0.62, -0.10)]
Week 24	120	3.2 (2.59)		112	2.0 (1.91)		
Week 24 chg	120	-3.8 (2.57)	-3.52 (0.19)	112	-4.2 (2.37)	-4.38 (0.19)	-0.86 (-1.39, -0.34) 0.001 [-0.35 (-0.61, -0.09)]
Week 25	114	2.8 (2.49)		115	2.0 (1.97)		
Week 25 chg	114	-4.1 (2.53)	-3.71 (0.19)	115	-4.3 (2.44)	-4.41 (0.19)	-0.70 (-1.23, -0.17) 0.010 [-0.28 (-0.54, -0.02)]
Week 26	112	2.9 (2.50)		118	2.1 (1.98)		
Week 26 chg	112	-4.0 (2.55)	-3.62 (0.19)	118	-4.2 (2.48)	-4.34 (0.19)	-0.72 (-1.25, -0.19) 0.008 [-0.29 (-0.55, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 6.9 (1.84)		57	57 6.7 (2.11)		
Week 1		53 5.7 (2.34)			56 5.5 (2.16)		
Week 1 chg		53 -1.2 (1.59)	-1.18 (0.31)		56 -1.2 (1.54)	-1.20 (0.30)	-0.02 (-0.88, 0.85) 0.970 [-0.01 (-0.39, 0.36)]
Week 2		53 5.1 (2.52)			57 4.8 (2.54)		
Week 2 chg		53 -1.8 (2.02)	-1.80 (0.31)		57 -1.8 (1.82)	-1.85 (0.30)	-0.05 (-0.91, 0.82) 0.910 [-0.03 (-0.40, 0.35)]
Week 3		52 4.5 (2.60)			57 4.1 (2.44)		
Week 3 chg		52 -2.4 (2.22)	-2.34 (0.32)		57 -2.6 (2.15)	-2.64 (0.30)	-0.31 (-1.17, 0.56) 0.488 [-0.14 (-0.52, 0.24)]
Week 4		52 4.1 (2.80)			57 3.7 (2.54)		
Week 4 chg		52 -2.8 (2.36)	-2.68 (0.32)		57 -2.9 (2.23)	-2.98 (0.30)	-0.30 (-1.16, 0.57) 0.498 [-0.13 (-0.51, 0.25)]
Week 5		52 3.8 (2.84)			55 3.4 (2.48)		
Week 5 chg		52 -3.1 (2.50)	-2.98 (0.32)		55 -3.4 (2.37)	-3.51 (0.31)	-0.53 (-1.40, 0.34) 0.230 [-0.22 (-0.60, 0.16)]
Week 6		51 3.9 (2.75)			55 3.3 (2.47)		
Week 6 chg		51 -3.0 (2.48)	-2.90 (0.32)		55 -3.5 (2.55)	-3.56 (0.31)	-0.67 (-1.54, 0.20) 0.132 [-0.27 (-0.65, 0.12)]
Week 7		51 3.7 (2.67)			54 3.1 (2.48)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	51	-3.2 (2.50)	-3.12 (0.32)	54	-3.7 (2.47)	-3.73 (0.31)	-0.61 (-1.48, 0.26) [-0.25 (-0.63, 0.14)]	0.167
Week 8	50	3.7 (2.67)		54	2.8 (2.39)			
Week 8 chg	50	-3.3 (2.45)	-3.12 (0.32)	54	-4.0 (2.46)	-4.04 (0.31)	-0.92 (-1.79, -0.05) [-0.37 (-0.76, 0.01)]	0.039
Week 9	50	3.6 (2.63)		54	2.6 (2.29)			
Week 9 chg	50	-3.3 (2.38)	-3.26 (0.32)	54	-4.1 (2.48)	-4.24 (0.31)	-0.98 (-1.85, -0.11) [-0.40 (-0.79, -0.01)]	0.028
Week 10	49	3.4 (2.66)		53	2.6 (2.28)			
Week 10 chg	49	-3.5 (2.36)	-3.35 (0.32)	53	-4.2 (2.51)	-4.29 (0.31)	-0.94 (-1.81, -0.07) [-0.38 (-0.78, 0.01)]	0.035
Week 11	50	3.3 (2.62)		53	2.5 (2.39)			
Week 11 chg	50	-3.6 (2.43)	-3.57 (0.32)	53	-4.3 (2.59)	-4.31 (0.31)	-0.74 (-1.62, 0.13) [-0.30 (-0.68, 0.09)]	0.095
Week 12	48	3.1 (2.61)		53	2.5 (2.43)			
Week 12 chg	48	-3.9 (2.57)	-3.71 (0.32)	53	-4.3 (2.75)	-4.33 (0.31)	-0.61 (-1.49, 0.26) [-0.23 (-0.62, 0.16)]	0.168
Week 13	48	2.8 (2.46)		51	2.3 (2.36)			
Week 13 chg	48	-4.1 (2.36)	-3.96 (0.32)	51	-4.4 (2.66)	-4.37 (0.31)	-0.41 (-1.29, 0.47) [-0.16 (-0.56, 0.23)]	0.359
Week 14	49	2.7 (2.38)		53	2.6 (2.42)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	49	-4.2 (2.39)	-4.08 (0.32)	53	-4.2 (2.71)	-4.26 (0.31)	-0.17 (-1.05, 0.70) 0.693 [-0.07 (-0.46, 0.32)]
Week 15	49	2.7 (2.59)		53	2.5 (2.52)		
Week 15 chg	49	-4.3 (2.39)	-4.08 (0.32)	53	-4.2 (2.82)	-4.32 (0.31)	-0.25 (-1.12, 0.63) 0.578 [-0.09 (-0.48, 0.29)]
Week 16	50	2.6 (2.46)		52	2.5 (2.42)		
Week 16 chg	50	-4.3 (2.28)	-4.07 (0.32)	52	-4.2 (2.68)	-4.35 (0.31)	-0.28 (-1.16, 0.59) 0.522 [-0.11 (-0.50, 0.27)]
Week 17	50	2.7 (2.49)		51	2.6 (2.66)		
Week 17 chg	50	-4.3 (2.46)	-4.18 (0.32)	51	-4.1 (2.83)	-4.27 (0.31)	-0.08 (-0.96, 0.79) 0.850 [-0.03 (-0.42, 0.36)]
Week 18	48	2.8 (2.82)		53	2.5 (2.60)		
Week 18 chg	48	-4.2 (2.57)	-4.10 (0.32)	53	-4.2 (2.91)	-4.33 (0.31)	-0.24 (-1.11, 0.64) 0.596 [-0.09 (-0.48, 0.31)]
Week 19	48	2.6 (2.77)		51	2.4 (2.67)		
Week 19 chg	48	-4.4 (2.52)	-4.27 (0.32)	51	-4.2 (3.00)	-4.34 (0.31)	-0.08 (-0.95, 0.80) 0.864 [-0.03 (-0.42, 0.37)]
Week 20	48	2.6 (2.77)		48	2.3 (2.47)		
Week 20 chg	48	-4.4 (2.52)	-4.27 (0.32)	48	-4.2 (2.98)	-4.28 (0.31)	-0.01 (-0.89, 0.87) 0.977 [-0.00 (-0.40, 0.40)]
Week 21	47	2.3 (2.41)		47	2.1 (2.35)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 21 chg	47	-4.7 (2.40)	-4.46 (0.32)	47	-4.5 (2.91)	-4.49 (0.31)	-0.04 (-0.92, 0.85) [-0.01 (-0.42, 0.39)]	0.933
Week 22	47	2.4 (2.68)		47	2.1 (2.25)			
Week 22 chg	47	-4.5 (2.62)	-4.30 (0.32)	47	-4.6 (2.88)	-4.56 (0.31)	-0.26 (-1.14, 0.63) [-0.09 (-0.50, 0.31)]	0.568
Week 23	48	2.3 (2.39)		48	2.1 (2.32)			
Week 23 chg	48	-4.5 (2.39)	-4.36 (0.32)	48	-4.5 (2.99)	-4.52 (0.31)	-0.16 (-1.04, 0.72) [-0.06 (-0.46, 0.34)]	0.722
Week 24	47	2.2 (2.42)		48	2.1 (2.24)			
Week 24 chg	47	-4.7 (2.48)	-4.47 (0.32)	48	-4.6 (2.91)	-4.58 (0.31)	-0.11 (-0.99, 0.77) [-0.04 (-0.44, 0.36)]	0.801
Week 25	47	2.1 (2.44)		51	2.1 (2.34)			
Week 25 chg	47	-4.7 (2.57)	-4.48 (0.32)	51	-4.5 (2.96)	-4.58 (0.31)	-0.10 (-0.98, 0.78) [-0.04 (-0.43, 0.36)]	0.827
Week 26	45	2.1 (2.40)		51	2.3 (2.36)			
Week 26 chg	45	-4.7 (2.49)	-4.39 (0.32)	51	-4.3 (3.05)	-4.41 (0.31)	-0.02 (-0.90, 0.87) [-0.01 (-0.41, 0.40)]	0.973

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 6.9 (1.52)		81	80 6.1 (2.08)		
Week 1		82 5.9 (1.78)			80 5.0 (2.23)		
Week 1 chg		82 -1.1 (1.44)	-0.94 (0.22)		80 -1.0 (1.40)	-1.13 (0.23)	-0.19 (-0.83, 0.44) 0.547 [-0.14 (-0.44, 0.17)]
Week 2		81 5.2 (2.14)			75 4.3 (2.38)		
Week 2 chg		81 -1.7 (1.97)	-1.54 (0.22)		75 -1.7 (1.80)	-1.89 (0.23)	-0.35 (-0.98, 0.29) 0.282 [-0.18 (-0.50, 0.13)]
Week 3		81 4.8 (2.20)			74 3.8 (2.28)		
Week 3 chg		81 -2.1 (2.15)	-1.95 (0.22)		74 -2.3 (1.89)	-2.41 (0.23)	-0.46 (-1.10, 0.18) 0.155 [-0.23 (-0.54, 0.09)]
Week 4		78 4.8 (2.23)			76 3.5 (2.28)		
Week 4 chg		78 -2.2 (2.11)	-1.94 (0.22)		76 -2.5 (1.92)	-2.69 (0.23)	-0.75 (-1.39, -0.11) 0.021 [-0.37 (-0.69, -0.05)]
Week 5		79 4.4 (2.32)			74 3.3 (2.39)		
Week 5 chg		79 -2.5 (2.26)	-2.24 (0.22)		74 -2.7 (1.95)	-2.87 (0.23)	-0.63 (-1.26, 0.01) 0.055 [-0.30 (-0.61, 0.02)]
Week 6		79 4.4 (2.35)			74 3.3 (2.41)		
Week 6 chg		79 -2.5 (2.27)	-2.24 (0.22)		74 -2.8 (1.94)	-2.94 (0.23)	-0.70 (-1.33, -0.06) 0.032 [-0.33 (-0.65, -0.01)]
Week 7		78 4.1 (2.26)			74 3.1 (2.30)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	78	-2.8 (2.31)	-2.53 (0.22)	74	-3.0 (2.09)	-3.19 (0.23)	-0.66 (-1.30, -0.03) 0.041 [-0.30 (-0.62, 0.02)]
Week 8	77	4.1 (2.32)		71	2.9 (2.22)		
Week 8 chg	77	-2.8 (2.22)	-2.51 (0.22)	71	-3.2 (2.05)	-3.38 (0.23)	-0.87 (-1.51, -0.23) 0.008 [-0.41 (-0.73, -0.08)]
Week 9	77	4.0 (2.39)		73	2.7 (2.17)		
Week 9 chg	77	-3.0 (2.31)	-2.65 (0.22)	73	-3.4 (1.99)	-3.55 (0.23)	-0.90 (-1.54, -0.26) 0.006 [-0.42 (-0.74, -0.09)]
Week 10	76	3.9 (2.46)		69	2.8 (2.32)		
Week 10 chg	76	-3.0 (2.43)	-2.76 (0.22)	69	-3.3 (2.04)	-3.47 (0.23)	-0.71 (-1.35, -0.06) 0.031 [-0.31 (-0.64, 0.01)]
Week 11	78	3.8 (2.34)		73	2.6 (2.09)		
Week 11 chg	78	-3.1 (2.36)	-2.81 (0.22)	73	-3.4 (1.92)	-3.60 (0.23)	-0.79 (-1.43, -0.15) 0.016 [-0.37 (-0.69, -0.04)]
Week 12	75	3.8 (2.30)		68	2.5 (2.05)		
Week 12 chg	75	-3.1 (2.34)	-2.77 (0.22)	68	-3.4 (1.97)	-3.76 (0.23)	-0.99 (-1.63, -0.35) 0.003 [-0.46 (-0.79, -0.12)]
Week 13	68	3.8 (2.29)		69	2.4 (1.95)		
Week 13 chg	68	-3.2 (2.24)	-2.80 (0.23)	69	-3.6 (1.88)	-3.81 (0.23)	-1.01 (-1.66, -0.36) 0.002 [-0.49 (-0.83, -0.15)]
Week 14	74	3.8 (2.35)		70	2.3 (1.99)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	74	-3.1 (2.21)	-2.86 (0.22)	70	-3.7 (1.87)	-3.87 (0.23)	-1.01 (-1.66, -0.37) [-0.49 (-0.83, -0.16)]	0.002
Week 15	74	3.7 (2.33)		70	2.3 (1.91)			
Week 15 chg	74	-3.3 (2.27)	-2.99 (0.22)	70	-3.7 (1.90)	-3.92 (0.23)	-0.92 (-1.57, -0.28) [-0.44 (-0.77, -0.11)]	0.005
Week 16	71	3.7 (2.27)		70	2.4 (1.99)			
Week 16 chg	71	-3.3 (2.20)	-2.93 (0.23)	70	-3.7 (2.01)	-3.87 (0.23)	-0.94 (-1.59, -0.30) [-0.45 (-0.78, -0.11)]	0.004
Week 17	71	3.9 (2.48)		70	2.2 (1.99)			
Week 17 chg	71	-3.1 (2.35)	-2.77 (0.23)	70	-3.8 (1.95)	-3.98 (0.23)	-1.21 (-1.86, -0.57) [-0.56 (-0.90, -0.22)]	<.001
Week 18	72	3.8 (2.46)		70	2.2 (1.94)			
Week 18 chg	72	-3.2 (2.39)	-2.85 (0.23)	70	-3.8 (1.93)	-4.03 (0.23)	-1.18 (-1.82, -0.54) [-0.54 (-0.88, -0.21)]	<.001
Week 19	71	3.8 (2.64)		66	2.0 (1.81)			
Week 19 chg	71	-3.2 (2.50)	-2.84 (0.23)	66	-4.0 (1.96)	-4.17 (0.23)	-1.33 (-1.98, -0.68) [-0.59 (-0.93, -0.25)]	<.001
Week 20	72	4.0 (2.64)		70	2.1 (1.85)			
Week 20 chg	72	-3.0 (2.57)	-2.67 (0.23)	70	-4.0 (1.97)	-4.12 (0.23)	-1.45 (-2.10, -0.81) [-0.64 (-0.97, -0.30)]	<.001
Week 21	71	3.8 (2.68)		68	2.1 (1.81)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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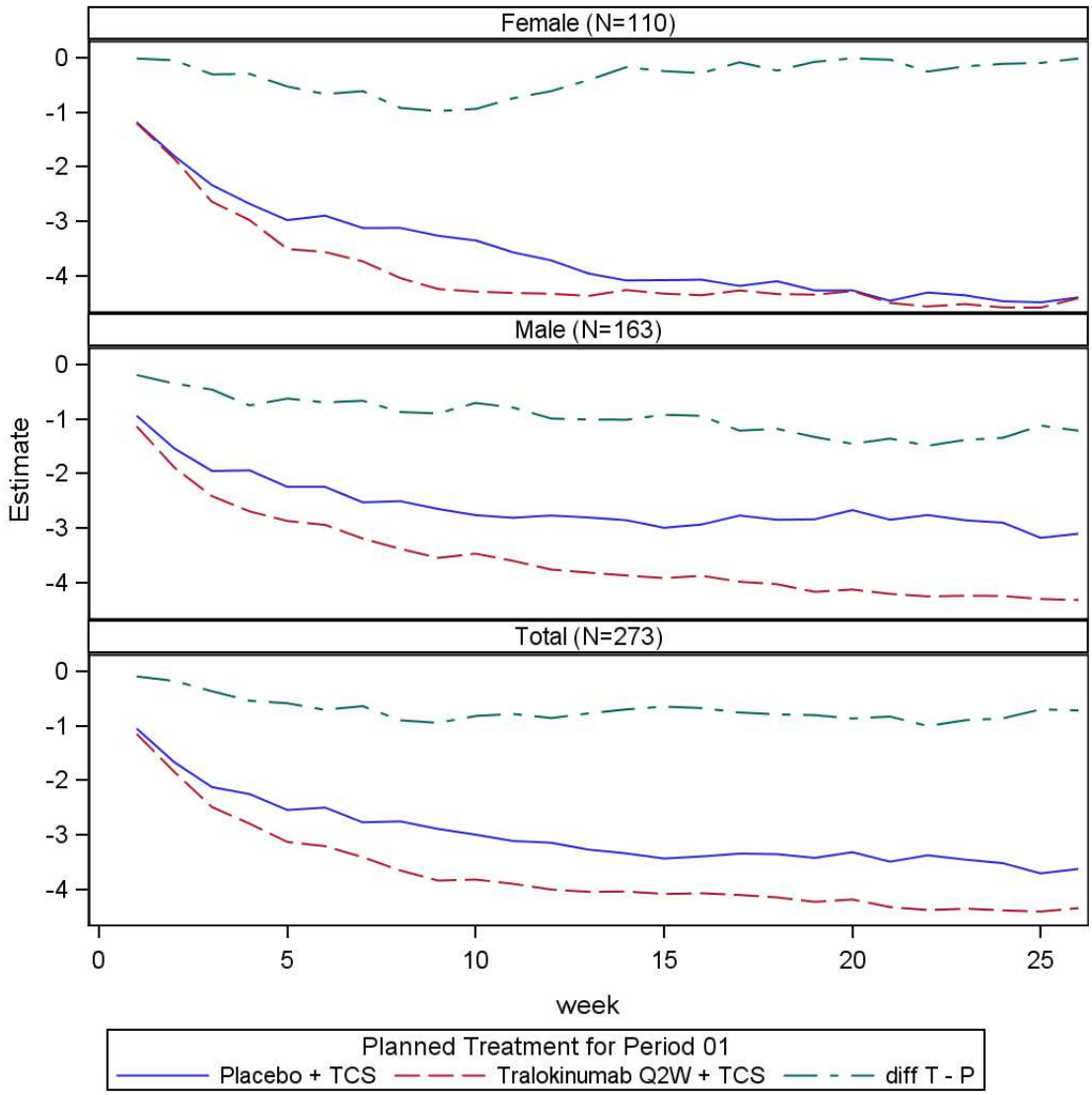
Table 1.4.418.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	71	-3.2 (2.60)	-2.85 (0.23)	68	-4.0 (1.91)	-4.20 (0.23)	-1.36 (-2.00, -0.71) <.001 [-0.59 (-0.93, -0.25)]
Week 22	73	3.9 (2.60)		69	1.9 (1.78)		
Week 22 chg	73	-3.1 (2.54)	-2.76 (0.23)	69	-4.1 (1.90)	-4.25 (0.23)	-1.49 (-2.14, -0.84) <.001 [-0.66 (-1.00, -0.32)]
Week 23	72	3.8 (2.64)		66	2.0 (1.78)		
Week 23 chg	72	-3.2 (2.54)	-2.86 (0.23)	66	-4.0 (1.95)	-4.24 (0.23)	-1.38 (-2.03, -0.73) <.001 [-0.61 (-0.95, -0.26)]
Week 24	73	3.8 (2.53)		64	1.9 (1.63)		
Week 24 chg	73	-3.3 (2.48)	-2.90 (0.23)	64	-4.0 (1.85)	-4.24 (0.23)	-1.34 (-1.99, -0.69) <.001 [-0.61 (-0.95, -0.26)]
Week 25	67	3.3 (2.43)		64	1.9 (1.64)		
Week 25 chg	67	-3.7 (2.44)	-3.18 (0.23)	64	-4.1 (1.94)	-4.30 (0.23)	-1.12 (-1.77, -0.47) <.001 [-0.51 (-0.86, -0.16)]
Week 26	67	3.5 (2.44)		67	1.9 (1.63)		
Week 26 chg	67	-3.5 (2.49)	-3.10 (0.23)	67	-4.1 (1.95)	-4.32 (0.23)	-1.21 (-1.86, -0.57) <.001 [-0.54 (-0.89, -0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.418.4.2: Total, Gender, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.4.420.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.24 (1.50)		138 -20.9 (16.72)	-21.09 (1.49)	-3.85 (-8.01, 0.31) 0.070 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.30 (1.51)		137 -30.8 (17.25)	-31.04 (1.50)	-4.74 (-8.92, -0.57) 0.026 [-0.27 (-0.50, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.83 (1.51)		134 -34.3 (17.49)	-34.46 (1.50)	-7.63 (-11.8, -3.43) <.001 [-0.42 (-0.66, -0.17)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.66 (1.51)		130 -36.6 (18.48)	-36.77 (1.51)	-8.11 (-12.3, -3.91) <.001 [-0.42 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.81 (1.51)		130 -38.5 (19.49)	-38.57 (1.51)	-7.76 (-12.0, -3.55) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.59 (1.52)		128 -39.5 (18.74)	-39.57 (1.52)	-7.98 (-12.2, -3.76) <.001 [-0.42 (-0.66, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0885
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.420.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14		126 36.0 (19.61)			127 28.3 (17.87)			
Week 14 chg		126 -34.8 (20.31)	-34.25 (1.53)		127 -41.8 (20.11)	-41.39 (1.52)	-7.14 (-11.4, -2.91) [-0.35 (-0.60, -0.11)]	<.001
Week 16		124 36.3 (18.78)			123 27.0 (16.90)			
Week 16 chg		124 -34.7 (19.94)	-33.90 (1.53)		123 -43.3 (19.46)	-42.70 (1.53)	-8.80 (-13.0, -4.55) [-0.45 (-0.70, -0.19)]	<.001
Week 18		116 36.8 (19.98)			115 25.1 (15.97)			
Week 18 chg		116 -34.1 (20.70)	-33.27 (1.55)		115 -44.8 (19.27)	-43.62 (1.55)	-10.36 (-14.7, -6.05) [-0.52 (-0.78, -0.26)]	<.001
Week 20		107 35.7 (19.63)			117 25.6 (16.83)			
Week 20 chg		107 -35.6 (20.01)	-34.07 (1.57)		117 -44.9 (18.80)	-43.48 (1.54)	-9.41 (-13.7, -5.08) [-0.49 (-0.75, -0.22)]	<.001
Week 22		112 35.6 (20.27)			114 23.3 (14.77)			
Week 22 chg		112 -35.5 (20.64)	-34.08 (1.56)		114 -46.8 (19.03)	-45.23 (1.55)	-11.15 (-15.5, -6.83) [-0.56 (-0.83, -0.30)]	<.001
Week 24		112 34.6 (19.86)			117 23.3 (15.61)			
Week 24 chg		112 -36.5 (20.30)	-34.56 (1.56)		117 -46.9 (18.55)	-45.65 (1.54)	-11.09 (-15.4, -6.78) [-0.57 (-0.84, -0.31)]	<.001
Week 26		118 33.1 (18.32)			125 23.8 (16.51)			
Week 26 chg		118 -38.1 (19.21)	-36.22 (1.54)		125 -46.3 (19.60)	-45.94 (1.52)	-9.72 (-14.0, -5.46) [-0.50 (-0.76, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0885
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.420.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 72.0 (13.89)		57	57 71.2 (11.89)		
Week 2		54 51.2 (19.83)			57 49.9 (18.26)		
Week 2 chg		54 -20.9 (16.80)	-20.64 (2.41)		57 -21.3 (17.56)	-21.62 (2.34)	-0.98 (-7.60, 5.65) 0.771 [-0.06 (-0.43, 0.32)]
Week 4		53 39.7 (18.34)			57 39.1 (17.96)		
Week 4 chg		53 -32.5 (17.59)	-31.94 (2.42)		57 -32.0 (17.88)	-32.48 (2.34)	-0.54 (-7.18, 6.10) 0.872 [-0.03 (-0.40, 0.34)]
Week 6		52 39.6 (18.46)			56 34.9 (16.90)		
Week 6 chg		52 -32.6 (18.93)	-32.18 (2.43)		56 -36.4 (18.50)	-36.52 (2.35)	-4.34 (-11.0, 2.33) 0.201 [-0.23 (-0.61, 0.15)]
Week 8		52 38.1 (21.15)			54 30.9 (15.55)		
Week 8 chg		52 -34.0 (20.66)	-33.64 (2.43)		54 -40.5 (17.74)	-40.12 (2.37)	-6.48 (-13.2, 0.21) 0.058 [-0.34 (-0.72, 0.05)]
Week 10		52 35.5 (20.36)			54 30.9 (17.80)		
Week 10 chg		52 -36.6 (20.85)	-36.21 (2.43)		54 -40.6 (20.25)	-40.35 (2.37)	-4.14 (-10.8, 2.55) 0.224 [-0.20 (-0.58, 0.18)]
Week 12		51 35.8 (19.18)			53 29.1 (16.11)		
Week 12 chg		51 -36.5 (21.25)	-36.47 (2.44)		53 -42.5 (16.83)	-42.24 (2.37)	-5.77 (-12.5, 0.94) 0.091 [-0.30 (-0.69, 0.08)]
Week 14		51 32.1 (21.19)			53 24.9 (14.57)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0885
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.420.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	51	-39.8 (21.32)	-39.99 (2.43)	53	-46.8 (18.11)	-45.97 (2.37)	-5.98 (-12.7, 0.73) 0.080 [-0.30 (-0.69, 0.08)]
Week 16		48 31.9 (20.57)			50 25.7 (16.80)		
Week 16 chg		48 -39.9 (21.41)	-39.52 (2.46)		50 -46.3 (20.53)	-45.47 (2.40)	-5.96 (-12.7, 0.82) 0.085 [-0.28 (-0.68, 0.11)]
Week 18		46 33.2 (20.83)			48 24.0 (16.88)		
Week 18 chg		46 -39.1 (21.18)	-38.96 (2.48)		48 -48.0 (20.72)	-45.63 (2.42)	-6.67 (-13.5, 0.15) 0.055 [-0.32 (-0.73, 0.09)]
Week 20		44 31.2 (20.49)			48 24.7 (16.43)		
Week 20 chg		44 -40.4 (20.19)	-40.59 (2.50)		48 -47.4 (19.18)	-45.02 (2.42)	-4.43 (-11.3, 2.42) 0.204 [-0.23 (-0.64, 0.18)]
Week 22		42 29.9 (20.94)			47 22.0 (13.47)		
Week 22 chg		42 -41.8 (21.29)	-40.57 (2.52)		47 -49.7 (18.68)	-47.33 (2.43)	-6.75 (-13.7, 0.15) 0.055 [-0.34 (-0.76, 0.08)]
Week 24		43 31.9 (21.16)			48 23.0 (16.41)		
Week 24 chg		43 -40.0 (22.22)	-38.10 (2.51)		48 -48.8 (19.93)	-46.82 (2.42)	-8.72 (-15.6, -1.85) 0.013 [-0.41 (-0.83, 0.00)]
Week 26		46 30.4 (19.13)			52 25.1 (15.94)		
Week 26 chg		46 -41.7 (21.62)	-39.83 (2.48)		52 -46.2 (19.45)	-45.36 (2.38)	-5.53 (-12.3, 1.25) 0.109 [-0.27 (-0.67, 0.13)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0885
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.4.420.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 70.0 (12.13)		81	81 69.5 (12.18)		
Week 2		83 54.8 (15.99)			81 48.9 (18.25)		
Week 2 chg		83 -15.3 (15.27)	-14.91 (1.89)		81 -20.6 (16.21)	-20.82 (1.92)	-5.91 (-11.2, -0.61) 0.029 [-0.38 (-0.68, -0.07)]
Week 4		81 46.5 (17.94)			80 39.2 (17.52)		
Week 4 chg		81 -23.2 (18.15)	-22.51 (1.90)		80 -30.0 (16.85)	-30.11 (1.92)	-7.61 (-12.9, -2.28) 0.005 [-0.43 (-0.75, -0.12)]
Week 6		80 45.9 (18.92)			78 36.4 (16.53)		
Week 6 chg		80 -24.1 (18.66)	-23.24 (1.91)		78 -32.7 (16.68)	-33.10 (1.93)	-9.86 (-15.2, -4.51) <.001 [-0.56 (-0.87, -0.24)]
Week 8		81 43.8 (19.19)			76 35.2 (17.81)		
Week 8 chg		81 -25.9 (18.83)	-25.31 (1.90)		76 -33.9 (18.62)	-34.48 (1.94)	-9.17 (-14.5, -3.82) <.001 [-0.49 (-0.81, -0.17)]
Week 10		79 41.7 (19.42)			76 31.7 (18.56)		
Week 10 chg		79 -28.2 (20.75)	-27.18 (1.91)		76 -37.0 (18.92)	-37.40 (1.94)	-10.22 (-15.6, -4.85) <.001 [-0.51 (-0.83, -0.19)]
Week 12		77 40.4 (17.45)			75 31.5 (18.71)		
Week 12 chg		77 -29.8 (18.15)	-28.29 (1.92)		75 -37.4 (19.83)	-37.78 (1.95)	-9.48 (-14.9, -4.09) <.001 [-0.50 (-0.82, -0.18)]
Week 14		75 38.7 (18.13)			74 30.7 (19.64)		

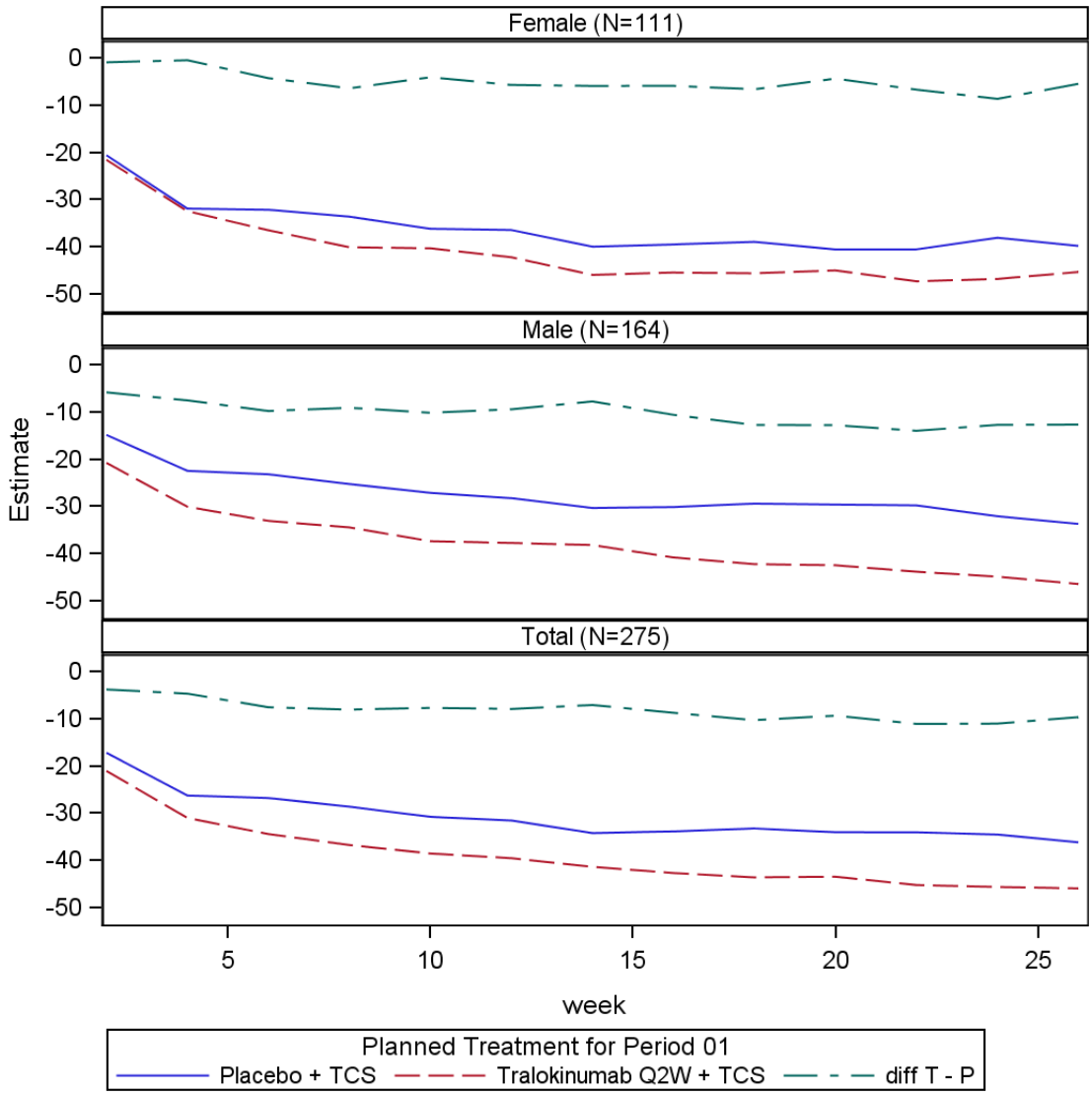
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0885
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.420.4.1: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	75	-31.3 (18.98)	-30.38 (1.93)	74	-38.2 (20.81)	-38.21 (1.95)	-7.83 (-13.2, -2.42) 0.005 [-0.39 (-0.72, -0.07)]
Week 16	76	39.1 (17.10)		73	27.9 (17.02)		
Week 16 chg	76	-31.4 (18.33)	-30.19 (1.93)	73	-41.2 (18.55)	-40.84 (1.96)	-10.65 (-16.1, -5.24) <.001 [-0.58 (-0.91, -0.25)]
Week 18	70	39.2 (19.19)		67	25.8 (15.37)		
Week 18 chg	70	-30.8 (19.87)	-29.45 (1.96)	67	-42.5 (17.96)	-42.26 (1.99)	-12.81 (-18.3, -7.30) <.001 [-0.68 (-1.02, -0.33)]
Week 20	63	38.8 (18.54)		69	26.2 (17.20)		
Week 20 chg	63	-32.2 (19.33)	-29.64 (2.00)	69	-43.2 (18.49)	-42.49 (1.98)	-12.85 (-18.4, -7.30) <.001 [-0.68 (-1.03, -0.33)]
Week 22	70	39.1 (19.18)		67	24.2 (15.65)		
Week 22 chg	70	-31.7 (19.42)	-29.82 (1.96)	67	-44.8 (19.15)	-43.86 (1.99)	-14.04 (-19.5, -8.53) <.001 [-0.73 (-1.07, -0.38)]
Week 24	69	36.3 (18.97)		69	23.5 (15.15)		
Week 24 chg	69	-34.2 (18.84)	-32.11 (1.97)	69	-45.6 (17.56)	-44.90 (1.98)	-12.79 (-18.3, -7.29) <.001 [-0.70 (-1.05, -0.36)]
Week 26	72	34.9 (17.70)		73	22.8 (16.96)		
Week 26 chg	72	-35.8 (17.26)	-33.74 (1.95)	73	-46.4 (19.84)	-46.46 (1.96)	-12.72 (-18.2, -7.28) <.001 [-0.68 (-1.02, -0.35)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0885
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.420.4.2: Total, Gender, change in SCORAD, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.4.422.4.1: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 2		131 9.2 (6.47)			132 8.5 (6.17)		
Week 2 chg		131 -7.2 (5.73)	-7.13 (0.44)		132 -7.5 (5.92)	-7.54 (0.44)	-0.41 (-1.63, 0.81) 0.508 [-0.07 (-0.31, 0.17)]
Week 4		130 7.8 (6.27)			135 6.7 (5.98)		
Week 4 chg		130 -8.6 (6.67)	-8.30 (0.44)		135 -9.0 (6.32)	-9.13 (0.44)	-0.82 (-2.04, 0.40) 0.185 [-0.13 (-0.37, 0.11)]
Week 6		123 7.3 (6.07)			126 6.0 (5.79)		
Week 6 chg		123 -8.9 (7.23)	-8.60 (0.45)		126 -10.0 (6.75)	-9.85 (0.44)	-1.25 (-2.48, -0.01) 0.048 [-0.18 (-0.43, 0.07)]
Week 8		127 6.9 (5.70)			128 5.4 (5.11)		
Week 8 chg		127 -9.4 (6.84)	-8.94 (0.44)		128 -10.6 (6.29)	-10.36 (0.44)	-1.41 (-2.64, -0.19) 0.024 [-0.22 (-0.46, 0.03)]
Week 12		123 6.8 (5.89)			124 5.0 (3.92)		
Week 12 chg		123 -9.8 (7.26)	-9.29 (0.45)		124 -10.6 (5.77)	-10.55 (0.44)	-1.26 (-2.50, -0.02) 0.046 [-0.19 (-0.44, 0.06)]
Week 16		120 6.5 (5.63)			118 4.5 (3.88)		
Week 16 chg		120 -10.0 (6.54)	-9.68 (0.45)		118 -11.0 (5.99)	-11.14 (0.45)	-1.46 (-2.71, -0.22) 0.022 [-0.23 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8136
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.422.4.1: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	6.2 (5.67)		111	4.1 (3.92)			
Week 20 chg	102	-9.9 (7.06)	-9.64 (0.46)	111	-11.4 (5.58)	-11.49 (0.45)	-1.85 (-3.13, -0.57) [-0.29 (-0.56, -0.02)]	0.005
Week 26	110	6.3 (5.26)		116	4.3 (4.31)			
Week 26 chg	110	-10.4 (6.56)	-9.61 (0.46)	116	-11.1 (6.17)	-11.28 (0.45)	-1.67 (-2.93, -0.41) [-0.26 (-0.52, -0.00)]	0.010

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8136
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.422.4.1: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 17.2 (6.62)		57	57 17.1 (6.83)		
Week 2		51 9.2 (6.84)			57 9.0 (6.86)		
Week 2 chg		51 -8.0 (5.70)	-8.12 (0.75)		57 -8.1 (6.26)	-8.10 (0.72)	0.02 (-2.03, 2.07) 0.985 [0.00 (-0.37, 0.38)]
Week 4		52 7.9 (6.95)			57 7.2 (6.61)		
Week 4 chg		52 -9.4 (6.53)	-9.13 (0.75)		57 -9.9 (6.49)	-9.95 (0.72)	-0.82 (-2.87, 1.23) 0.430 [-0.13 (-0.50, 0.25)]
Week 6		48 6.7 (5.67)			55 6.3 (6.41)		
Week 6 chg		48 -10.8 (6.72)	-10.12 (0.76)		55 -10.9 (7.58)	-10.75 (0.72)	-0.63 (-2.70, 1.44) 0.548 [-0.09 (-0.48, 0.30)]
Week 8		49 6.4 (5.79)			53 5.7 (5.62)		
Week 8 chg		49 -10.8 (6.55)	-10.20 (0.76)		53 -11.7 (6.34)	-11.43 (0.73)	-1.23 (-3.30, 0.84) 0.241 [-0.19 (-0.58, 0.20)]
Week 12		48 6.4 (6.37)			51 5.2 (4.58)		
Week 12 chg		48 -11.0 (7.66)	-10.74 (0.76)		51 -11.7 (5.90)	-11.54 (0.73)	-0.80 (-2.88, 1.28) 0.448 [-0.12 (-0.51, 0.28)]
Week 16		45 6.0 (6.53)			47 4.6 (4.28)		
Week 16 chg		45 -11.4 (6.88)	-11.20 (0.77)		47 -12.3 (6.39)	-12.43 (0.74)	-1.23 (-3.34, 0.87) 0.250 [-0.19 (-0.60, 0.22)]
Week 20		41 5.3 (5.92)			47 4.4 (4.83)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8136
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.422.4.1: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	41	-11.4 (6.71)	-11.71 (0.78)	47	-12.2 (5.99)	-12.54 (0.74)	-0.84 (-2.96, 1.29) [-0.13 (-0.55, 0.29)]	0.438
Week 26	42	5.6 (5.60)		49	4.5 (4.95)			
Week 26 chg	42	-12.2 (6.79)	-10.86 (0.78)	49	-12.4 (6.82)	-12.61 (0.74)	-1.75 (-3.86, 0.37) [-0.26 (-0.67, 0.16)]	0.105

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8136
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.422.4.1: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	81 15.8 (6.11)		81	80 15.0 (6.22)			
Week 2		80 9.2 (6.27)			75 8.1 (5.61)			
Week 2 chg		80 -6.8 (5.73)	-6.45 (0.54)		75 -7.1 (5.65)	-7.19 (0.55)	-0.74 (-2.27, 0.78) [-0.13 (-0.45, 0.19)]	0.340
Week 4		78 7.7 (5.83)			78 6.4 (5.50)			
Week 4 chg		78 -8.1 (6.76)	-7.71 (0.55)		78 -8.4 (6.16)	-8.60 (0.55)	-0.89 (-2.41, 0.64) [-0.14 (-0.45, 0.18)]	0.253
Week 6		75 7.7 (6.32)			71 5.8 (5.30)			
Week 6 chg		75 -7.7 (7.34)	-7.56 (0.55)		71 -9.3 (6.00)	-9.24 (0.56)	-1.68 (-3.23, -0.13) [-0.25 (-0.58, 0.08)]	0.033
Week 8		78 7.2 (5.67)			75 5.2 (4.75)			
Week 8 chg		78 -8.5 (6.91)	-8.07 (0.55)		75 -9.8 (6.17)	-9.64 (0.55)	-1.57 (-3.10, -0.04) [-0.24 (-0.56, 0.08)]	0.045
Week 12		75 7.1 (5.60)			73 4.9 (3.42)			
Week 12 chg		75 -9.0 (6.92)	-8.31 (0.55)		73 -9.9 (5.59)	-9.89 (0.56)	-1.58 (-3.12, -0.03) [-0.25 (-0.57, 0.07)]	0.045
Week 16		75 6.8 (5.04)			71 4.4 (3.62)			
Week 16 chg		75 -9.1 (6.23)	-8.65 (0.55)		71 -10.1 (5.60)	-10.26 (0.56)	-1.61 (-3.16, -0.06) [-0.27 (-0.60, 0.05)]	0.042
Week 20		61 6.9 (5.46)			64 3.8 (3.09)			

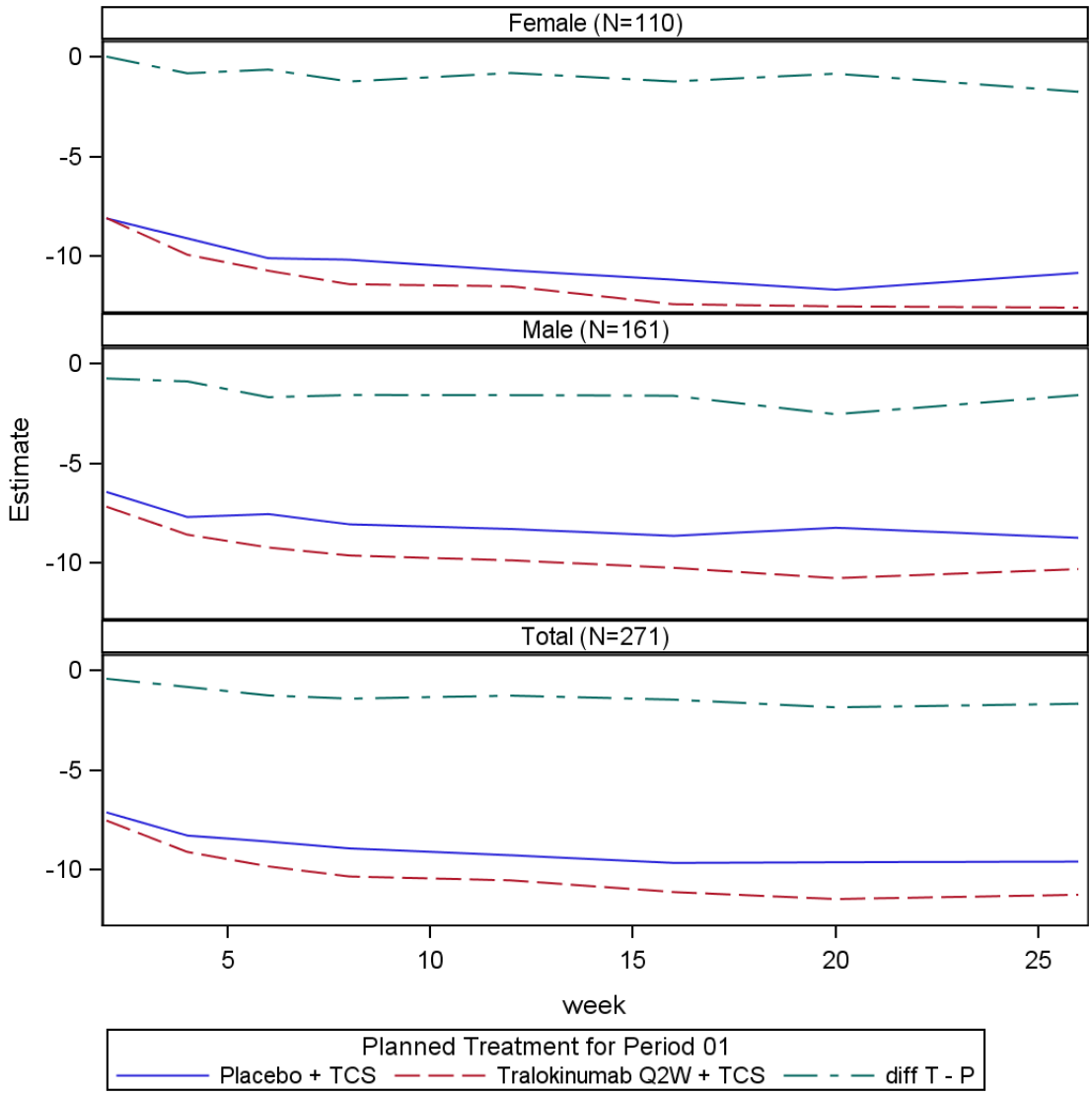
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8136
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.422.4.1: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	61	-9.0 (7.17)	-8.25 (0.58)	64	-10.8 (5.24)	-10.78 (0.57)	-2.54 (-4.14, -0.93) [-0.41 (-0.76, -0.05)]	0.002
Week 26	68	6.6 (5.05)		67	4.1 (3.81)			
Week 26 chg	68	-9.3 (6.22)	-8.76 (0.56)	67	-10.2 (5.52)	-10.33 (0.57)	-1.57 (-3.15, 0.01) [-0.27 (-0.61, 0.07)]	0.051

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8136
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.422.4.2: Total, Gender, change in DLQI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.4.423.4.1: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total									
Total									
Baseline	137	134	20.9 (5.72)		138	135	21.3 (5.12)		
Week 2		130	15.1 (6.91)			130	13.5 (6.31)		
Week 2 chg		130	-5.9 (6.29)	-5.97 (0.55)		130	-7.7 (5.43)	-7.67 (0.55)	-1.71 (-3.23, -0.18) 0.029 [-0.29 (-0.53, -0.05)]
Week 4		130	13.8 (7.45)			133	11.6 (6.30)		
Week 4 chg		130	-7.1 (7.56)	-7.11 (0.55)		133	-9.7 (6.02)	-9.53 (0.55)	-2.42 (-3.94, -0.89) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123	13.5 (7.81)			124	10.9 (5.95)		
Week 6 chg		123	-7.2 (8.29)	-7.29 (0.56)		124	-10.6 (6.27)	-10.35 (0.56)	-3.07 (-4.61, -1.52) <.001 [-0.42 (-0.67, -0.17)]
Week 8		127	13.1 (7.02)			126	9.9 (5.79)		
Week 8 chg		127	-7.6 (7.95)	-7.70 (0.55)		126	-11.5 (6.10)	-11.16 (0.55)	-3.46 (-5.00, -1.92) <.001 [-0.49 (-0.74, -0.24)]
Week 12		123	13.0 (7.39)			122	9.2 (5.72)		
Week 12 chg		123	-8.0 (8.26)	-7.91 (0.56)		122	-12.4 (6.20)	-11.78 (0.56)	-3.88 (-5.43, -2.33) <.001 [-0.53 (-0.79, -0.28)]
Week 16		120	13.0 (7.69)			116	9.1 (5.58)		
Week 16 chg		120	-8.0 (8.09)	-8.08 (0.56)		116	-12.2 (6.39)	-11.81 (0.56)	-3.73 (-5.30, -2.17) <.001 [-0.51 (-0.77, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7845
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.423.4.1: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	12.3 (7.64)		109	9.0 (5.60)			
Week 20 chg	102	-8.3 (7.60)	-8.25 (0.58)	109	-12.2 (6.08)	-11.90 (0.57)	-3.65 (-5.25, -2.05) [-0.53 (-0.81, -0.26)]	<.001
Week 26	110	11.8 (7.82)		114	8.2 (5.65)			
Week 26 chg	110	-8.9 (8.23)	-8.77 (0.57)	114	-12.8 (6.59)	-12.64 (0.57)	-3.86 (-5.44, -2.28) [-0.52 (-0.79, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7845
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.423.4.1: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female											
Baseline	54	53	21.2 (5.64)			57	55	21.7 (5.28)			
Week 2		50	14.8 (6.68)				55	14.0 (5.72)			
Week 2 chg		50	-6.6 (6.00)	-6.71	(0.89)		55	-7.7 (5.68)	-7.62	(0.86)	-0.91 (-3.36, 1.54) 0.463 [-0.16 (-0.54, 0.23)]
Week 4		52	13.6 (6.89)				55	11.6 (6.06)			
Week 4 chg		52	-7.6 (7.63)	-7.72	(0.89)		55	-10.1 (6.54)	-10.02	(0.86)	-2.31 (-4.75, 0.14) 0.064 [-0.33 (-0.71, 0.06)]
Week 6		48	12.9 (7.11)				53	11.6 (5.69)			
Week 6 chg		48	-8.3 (8.58)	-8.42	(0.90)		53	-10.4 (6.71)	-10.11	(0.87)	-1.69 (-4.17, 0.79) 0.182 [-0.22 (-0.61, 0.17)]
Week 8		49	12.9 (6.64)				51	10.1 (6.04)			
Week 8 chg		49	-8.2 (8.40)	-8.38	(0.90)		51	-12.0 (5.88)	-11.50	(0.88)	-3.11 (-5.60, -0.63) 0.014 [-0.43 (-0.83, -0.03)]
Week 12		48	12.9 (7.36)				49	9.2 (6.06)			
Week 12 chg		48	-8.4 (8.40)	-8.65	(0.90)		49	-13.1 (6.52)	-12.37	(0.89)	-3.72 (-6.22, -1.22) 0.004 [-0.50 (-0.90, -0.09)]
Week 16		45	12.5 (7.88)				45	8.8 (5.27)			
Week 16 chg		45	-8.9 (8.77)	-9.03	(0.92)		45	-13.2 (6.73)	-12.86	(0.91)	-3.83 (-6.37, -1.28) 0.003 [-0.49 (-0.91, -0.07)]
Week 20		41	11.6 (7.56)				45	9.6 (5.80)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7845
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.423.4.1: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	41	-9.0 (8.41)	-9.75 (0.94)	45	-12.3 (6.84)	-11.89 (0.91)	-2.14 (-4.72, 0.44) [-0.28 (-0.71, 0.14)]	0.104
Week 26	42	11.4 (7.95)		47	9.2 (5.82)			
Week 26 chg	42	-9.8 (8.61)	-9.26 (0.93)	47	-12.3 (7.18)	-12.39 (0.90)	-3.12 (-5.67, -0.57) [-0.40 (-0.82, 0.02)]	0.017

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7845
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.423.4.1: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	81 20.6 (5.80)		81	80 21.0 (5.02)		
Week 2		80 15.3 (7.09)			75 13.2 (6.73)		
Week 2 chg		80 -5.5 (6.46)	-5.48 (0.70)		75 -7.8 (5.27)	-7.74 (0.71)	-2.25 (-4.22, -0.29) 0.025 [-0.38 (-0.70, -0.06)]
Week 4		78 13.8 (7.85)			78 11.6 (6.51)		
Week 4 chg		78 -6.7 (7.54)	-6.72 (0.71)		78 -9.3 (5.65)	-9.20 (0.71)	-2.48 (-4.44, -0.51) 0.014 [-0.37 (-0.69, -0.05)]
Week 6		75 13.9 (8.24)			71 10.3 (6.13)		
Week 6 chg		75 -6.4 (8.07)	-6.54 (0.71)		71 -10.8 (5.96)	-10.56 (0.72)	-4.02 (-6.02, -2.02) <.001 [-0.56 (-0.90, -0.23)]
Week 8		78 13.3 (7.29)			75 9.8 (5.66)		
Week 8 chg		78 -7.2 (7.68)	-7.24 (0.71)		75 -11.2 (6.27)	-10.95 (0.72)	-3.71 (-5.68, -1.73) <.001 [-0.53 (-0.85, -0.21)]
Week 12		75 13.1 (7.46)			73 9.2 (5.52)		
Week 12 chg		75 -7.8 (8.22)	-7.39 (0.71)		73 -11.9 (5.97)	-11.43 (0.72)	-4.04 (-6.03, -2.05) <.001 [-0.56 (-0.89, -0.23)]
Week 16		75 13.2 (7.61)			71 9.2 (5.79)		
Week 16 chg		75 -7.5 (7.67)	-7.47 (0.71)		71 -11.5 (6.12)	-11.16 (0.72)	-3.70 (-5.70, -1.70) <.001 [-0.53 (-0.86, -0.20)]
Week 20		61 12.8 (7.73)			64 8.5 (5.46)		

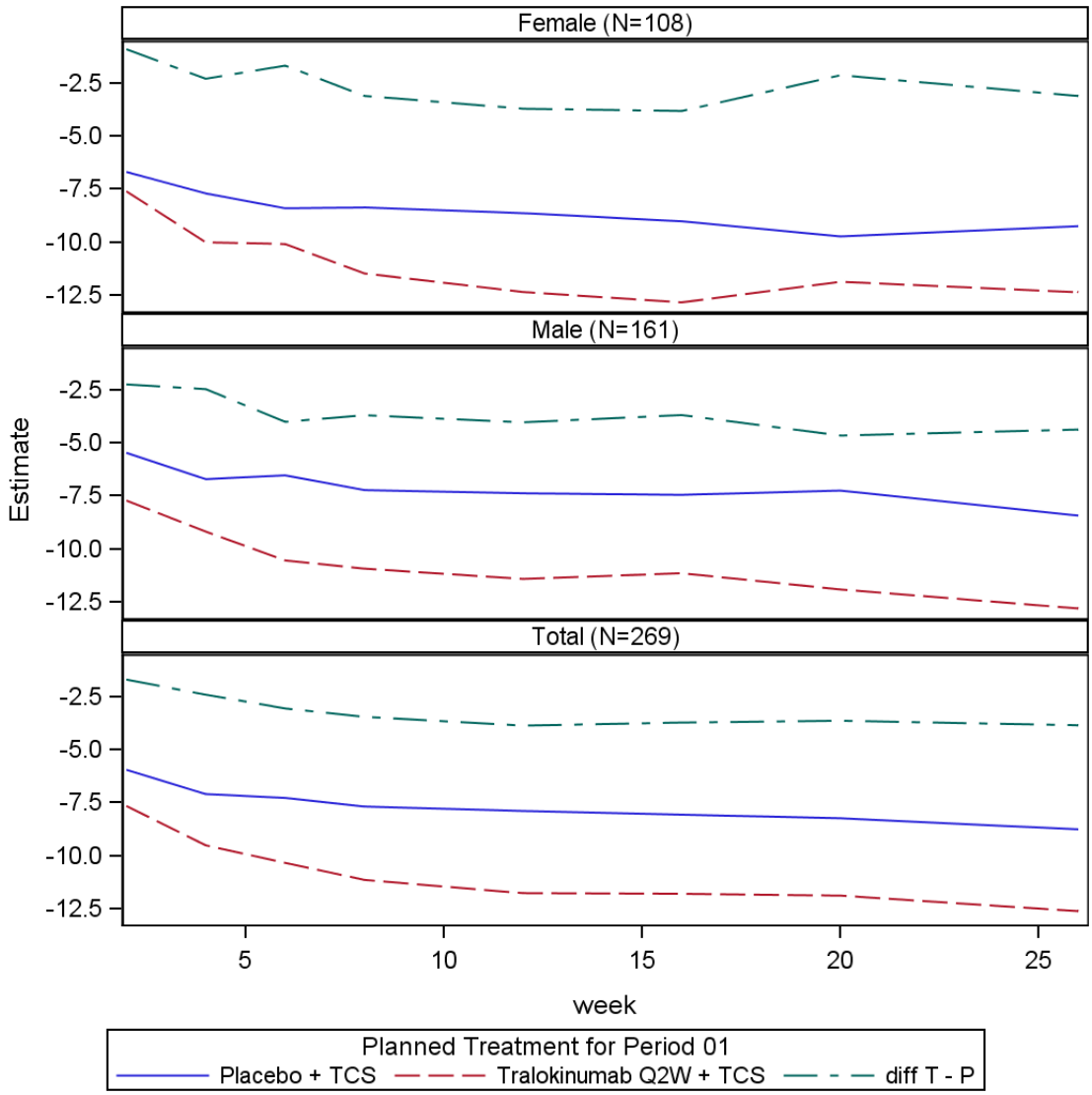
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7845
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.423.4.1: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	61	-7.8 (7.03)	-7.26 (0.74)	64	-12.2 (5.54)	-11.93 (0.74)	-4.67 (-6.73, -2.60) [-0.74 (-1.10, -0.38)]	<.001
Week 26	68	12.1 (7.79)		67	7.6 (5.47)			
Week 26 chg	68	-8.3 (7.99)	-8.44 (0.73)	67	-13.2 (6.16)	-12.83 (0.73)	-4.38 (-6.41, -2.35) [-0.61 (-0.96, -0.27)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7845
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.4.423.4.2: Total, Gender, change in POEM, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.4.428.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.41 (0.22)		138 -2.8 (2.87)	-2.87 (0.22)	-0.45 (-1.08, 0.17) 0.153 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.23 (0.23)		137 -3.8 (2.99)	-3.80 (0.22)	-0.58 (-1.20, 0.05) 0.071 [-0.18 (-0.42, 0.06)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.15 (0.23)		134 -4.1 (2.81)	-4.07 (0.23)	-0.92 (-1.55, -0.29) 0.004 [-0.30 (-0.54, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.50 (0.23)		130 -4.4 (2.91)	-4.34 (0.23)	-0.84 (-1.47, -0.21) 0.009 [-0.27 (-0.51, -0.03)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.65 (0.23)		130 -4.5 (2.93)	-4.46 (0.23)	-0.81 (-1.44, -0.18) 0.012 [-0.26 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.73 (0.23)		128 -4.6 (2.96)	-4.55 (0.23)	-0.83 (-1.46, -0.19) 0.011 [-0.26 (-0.51, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3478
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.428.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	126	2.8 (2.94)		127	2.3 (2.60)			
Week 14 chg	126	-4.0 (3.48)	-3.88 (0.23)	127	-4.4 (3.07)	-4.33 (0.23)	-0.45 (-1.09, 0.18) [-0.14 (-0.38, 0.11)]	0.161
Week 16	124	2.7 (2.77)		123	1.9 (2.39)			
Week 16 chg	124	-4.1 (3.25)	-3.93 (0.23)	123	-4.7 (2.92)	-4.64 (0.23)	-0.72 (-1.36, -0.08) [-0.23 (-0.48, 0.02)]	0.027

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3478
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.428.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 7.3 (1.97)		57	57 7.1 (2.25)		
Week 2		54 4.2 (3.12)			57 4.2 (2.80)		
Week 2 chg		54 -3.1 (2.99)	-3.05 (0.38)		57 -2.9 (2.92)	-2.95 (0.37)	0.09 (-0.95, 1.14) 0.861 [0.03 (-0.34, 0.40)]
Week 4		53 3.1 (2.91)			57 3.2 (2.97)		
Week 4 chg		53 -4.2 (3.10)	-4.08 (0.38)		57 -3.9 (3.32)	-4.01 (0.37)	0.07 (-0.98, 1.11) 0.899 [0.02 (-0.35, 0.40)]
Week 6		52 3.3 (2.98)			56 2.8 (2.80)		
Week 6 chg		52 -4.1 (3.19)	-3.95 (0.38)		56 -4.3 (3.01)	-4.41 (0.37)	-0.46 (-1.51, 0.59) 0.391 [-0.15 (-0.53, 0.23)]
Week 8		52 2.9 (2.81)			54 2.4 (2.62)		
Week 8 chg		52 -4.5 (3.12)	-4.35 (0.38)		54 -4.7 (2.99)	-4.78 (0.37)	-0.42 (-1.48, 0.63) 0.428 [-0.14 (-0.52, 0.24)]
Week 10		52 2.8 (2.92)			54 2.3 (2.73)		
Week 10 chg		52 -4.6 (3.19)	-4.45 (0.38)		54 -4.8 (3.09)	-4.90 (0.37)	-0.45 (-1.50, 0.61) 0.402 [-0.14 (-0.52, 0.24)]
Week 12		51 2.5 (2.80)			53 2.2 (2.80)		
Week 12 chg		51 -4.9 (3.27)	-4.72 (0.38)		53 -5.0 (3.16)	-5.05 (0.37)	-0.33 (-1.39, 0.73) 0.537 [-0.10 (-0.49, 0.28)]
Week 14		51 2.4 (3.02)			53 2.3 (2.97)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3478
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.428.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	51	-5.0 (3.24)	-4.88 (0.38)	53	-4.8 (3.38)	-4.83 (0.37)	0.06 (-1.00, 1.11) [0.02 (-0.37, 0.40)]	0.917
Week 16	48	1.9 (2.50)		50	2.1 (2.82)			
Week 16 chg	48	-5.5 (2.86)	-5.20 (0.39)	50	-4.9 (3.30)	-5.08 (0.38)	0.12 (-0.95, 1.19) [0.04 (-0.36, 0.44)]	0.822

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3478
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.428.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 6.4 (2.28)		81	81 6.4 (2.41)		
Week 2		83 4.4 (2.50)			81 3.6 (2.64)		
Week 2 chg		83 -2.0 (2.92)	-1.98 (0.28)		81 -2.8 (2.84)	-2.82 (0.28)	-0.84 (-1.61, -0.07) 0.032 [-0.29 (-0.60, 0.02)]
Week 4		81 3.6 (2.64)			80 2.6 (2.45)		
Week 4 chg		81 -2.7 (3.30)	-2.65 (0.28)		80 -3.7 (2.74)	-3.68 (0.28)	-1.04 (-1.81, -0.26) 0.009 [-0.34 (-0.65, -0.03)]
Week 6		80 3.7 (2.83)			78 2.4 (2.41)		
Week 6 chg		80 -2.7 (3.27)	-2.59 (0.28)		78 -3.9 (2.67)	-3.85 (0.28)	-1.26 (-2.04, -0.48) 0.002 [-0.42 (-0.74, -0.11)]
Week 8		81 3.4 (2.61)			76 2.2 (2.37)		
Week 8 chg		81 -3.0 (3.27)	-2.92 (0.28)		76 -4.2 (2.86)	-4.06 (0.28)	-1.13 (-1.91, -0.35) 0.004 [-0.37 (-0.68, -0.05)]
Week 10		79 3.2 (2.69)			76 2.1 (2.44)		
Week 10 chg		79 -3.2 (3.40)	-3.10 (0.28)		76 -4.2 (2.80)	-4.17 (0.28)	-1.07 (-1.85, -0.29) 0.007 [-0.34 (-0.66, -0.03)]
Week 12		77 3.2 (2.58)			75 2.1 (2.25)		
Week 12 chg		77 -3.2 (3.27)	-3.05 (0.28)		75 -4.3 (2.81)	-4.23 (0.28)	-1.18 (-1.96, -0.39) 0.003 [-0.39 (-0.71, -0.07)]
Week 14		75 3.0 (2.88)			74 2.3 (2.31)		

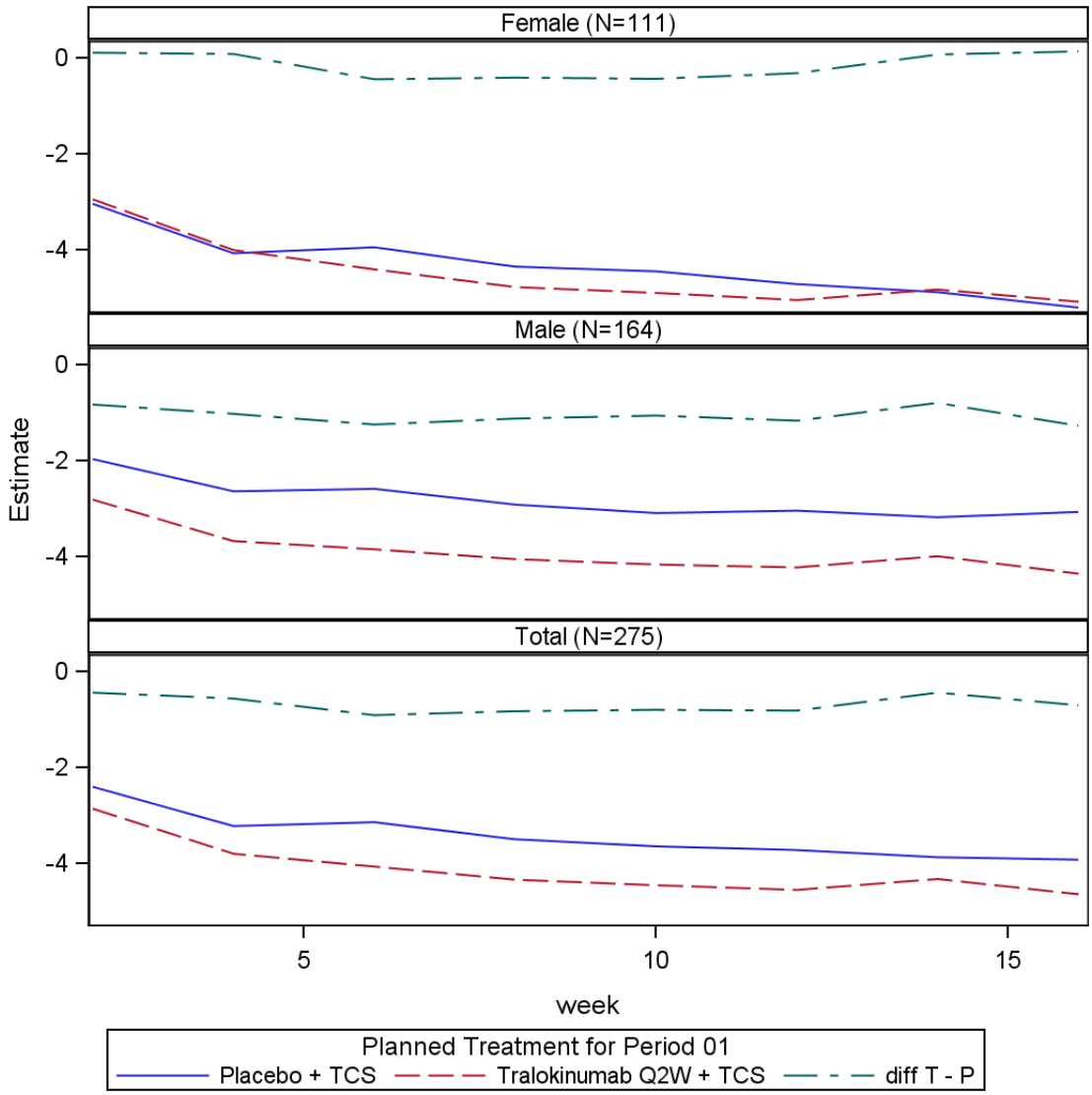
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3478
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.428.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	75	-3.4 (3.50)	-3.19 (0.28)	74	-4.1 (2.81)	-3.99 (0.28)	-0.81 (-1.60, -0.02) [-0.25 (-0.58, 0.07)]	0.044
Week 16	76	3.2 (2.82)		73	1.8 (2.07)			
Week 16 chg	76	-3.2 (3.20)	-3.08 (0.28)	73	-4.5 (2.64)	-4.36 (0.28)	-1.28 (-2.07, -0.50) [-0.44 (-0.76, -0.11)]	0.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3478
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.428.4.2: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.4.429.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.80 (1.50)		133	17.3 (19.49)	18.41 (1.49)	2.61 (-1.55, 6.77) 0.219 [0.13 (-0.12, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.37 (1.51)		126	18.4 (21.17)	19.36 (1.51)	2.99 (-1.23, 7.20) 0.165 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.37 (1.53)		122	18.7 (21.48)	19.47 (1.53)	2.11 (-2.15, 6.37) 0.332 [0.09 (-0.16, 0.35)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.72 (1.54)		116	17.7 (22.49)	19.74 (1.55)	5.02 (0.71, 9.33) 0.022 [0.20 (-0.05, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7975
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.429.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female										
Baseline	54	53	48.5 (21.94)		57	55	56.9 (21.30)			
Week 4		53	70.6 (19.35)			55	74.3 (16.30)			
Week 4 chg		53	22.1 (22.96)	19.11 (2.66)		55	17.5 (22.60)	20.28 (2.61)	1.16 (-6.26, 8.59) [0.05 (-0.33, 0.43)]	0.758
Week 8		49	71.4 (21.08)			51	74.0 (17.88)			
Week 8 chg		49	22.4 (29.42)	18.22 (2.73)		51	17.2 (24.36)	20.33 (2.67)	2.10 (-5.49, 9.70) [0.08 (-0.31, 0.47)]	0.586
Week 12		48	71.1 (20.82)			49	76.2 (16.89)			
Week 12 chg		48	22.1 (28.01)	18.99 (2.74)		49	20.2 (25.01)	22.73 (2.70)	3.74 (-3.91, 11.39) [0.14 (-0.26, 0.54)]	0.336
Week 16		45	70.4 (24.61)			45	73.3 (19.53)			
Week 16 chg		45	21.4 (30.03)	17.71 (2.80)		45	16.2 (25.51)	20.25 (2.78)	2.55 (-5.30, 10.39) [0.09 (-0.32, 0.50)]	0.523

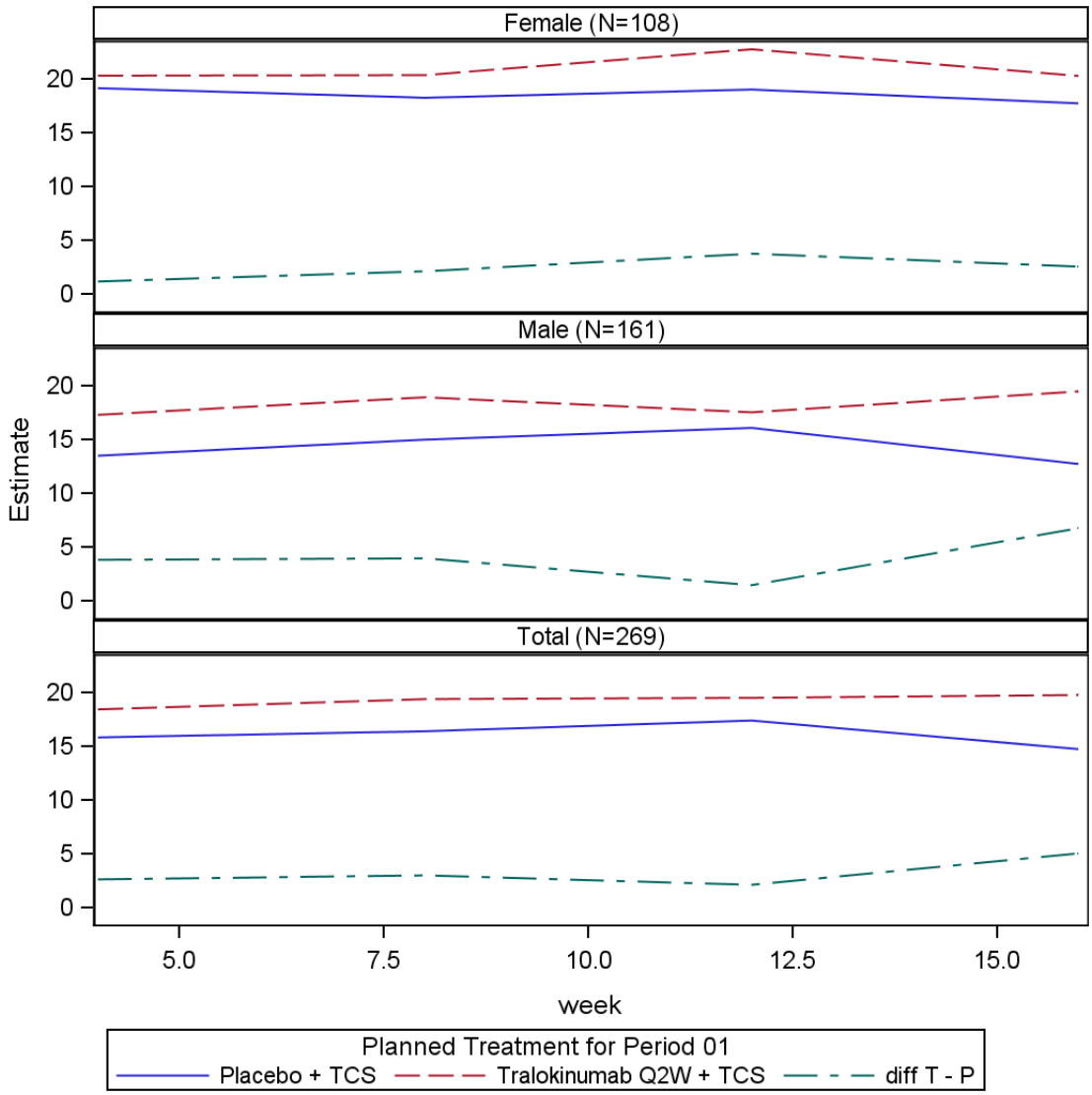
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7975
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.429.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male										
Baseline	83	81	55.1 (21.74)		81	80	56.4 (19.01)			
Week 4		78	68.9 (16.42)			78	73.4 (17.14)			
Week 4 chg		78	14.1 (20.58)	13.47 (1.77)		78	17.1 (17.13)	17.27 (1.77)	3.80 (-1.12, 8.72) [0.20 (-0.11, 0.52)]	0.130
Week 8		78	70.8 (17.24)			75	75.8 (15.10)			
Week 8 chg		78	15.6 (21.73)	14.96 (1.76)		75	19.3 (18.82)	18.90 (1.79)	3.94 (-1.02, 8.89) [0.19 (-0.12, 0.51)]	0.119
Week 12		75	71.2 (18.38)			73	74.8 (15.36)			
Week 12 chg		75	17.1 (19.08)	16.05 (1.79)		73	17.8 (18.87)	17.50 (1.81)	1.44 (-3.56, 6.45) [0.08 (-0.25, 0.40)]	0.571
Week 16		75	68.4 (20.11)			71	77.1 (15.15)			
Week 16 chg		75	13.9 (24.34)	12.71 (1.78)		71	18.6 (20.48)	19.45 (1.82)	6.74 (1.71, 11.77) [0.30 (-0.03, 0.63)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7975
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.429.4.2: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.4.430.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.83 (1.52)		133	17.3 (19.49)	18.45 (1.50)	2.62 (-1.59, 6.82) 0.222 [0.13 (-0.11, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.39 (1.53)		126	18.4 (21.17)	19.38 (1.53)	2.99 (-1.26, 7.24) 0.168 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.49 (1.54)		122	18.7 (21.48)	19.49 (1.54)	1.99 (-2.30, 6.29) 0.362 [0.09 (-0.16, 0.34)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.83 (1.55)		116	17.7 (22.49)	19.65 (1.57)	4.82 (0.48, 9.16) 0.030 [0.19 (-0.06, 0.45)]
Week 20		103	72.7 (20.07)			108	77.3 (14.52)		
Week 20 chg		103	19.3 (25.56)	17.99 (1.61)		108	21.6 (20.57)	21.18 (1.59)	3.20 (-1.26, 7.65) 0.159 [0.14 (-0.13, 0.41)]
Week 26		113	72.4 (20.84)			116	76.4 (17.02)		
Week 26 chg		113	20.5 (25.83)	17.77 (1.58)		116	19.5 (21.18)	20.31 (1.56)	2.53 (-1.84, 6.90) 0.256 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2785
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.430.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female									
Baseline	54	53	48.5 (21.94)		57	55	56.9 (21.30)		
Week 4		53	70.6 (19.35)			55	74.3 (16.30)		
Week 4 chg		53	22.1 (22.96)	19.10 (2.70)		55	17.5 (22.60)	20.35 (2.65)	1.25 (-6.28, 8.78) 0.744 [0.05 (-0.32, 0.43)]
Week 8		49	71.4 (21.08)			51	74.0 (17.88)		
Week 8 chg		49	22.4 (29.42)	18.34 (2.76)		51	17.2 (24.36)	20.36 (2.71)	2.02 (-5.67, 9.72) 0.605 [0.08 (-0.32, 0.47)]
Week 12		48	71.1 (20.82)			49	76.2 (16.89)		
Week 12 chg		48	22.1 (28.01)	19.15 (2.78)		49	20.2 (25.01)	22.84 (2.73)	3.69 (-4.05, 11.43) 0.348 [0.14 (-0.26, 0.54)]
Week 16		45	70.4 (24.61)			45	73.3 (19.53)		
Week 16 chg		45	21.4 (30.03)	17.72 (2.83)		45	16.2 (25.51)	20.14 (2.80)	2.41 (-5.50, 10.33) 0.549 [0.09 (-0.33, 0.50)]
Week 20		41	76.5 (20.96)			44	77.1 (16.26)		
Week 20 chg		41	25.8 (27.15)	23.95 (2.89)		44	22.0 (25.68)	22.67 (2.81)	-1.29 (-9.27, 6.70) 0.752 [-0.05 (-0.47, 0.38)]
Week 26		43	76.5 (23.06)			49	75.7 (20.48)		
Week 26 chg		43	29.4 (27.39)	23.35 (2.88)		49	18.5 (25.21)	21.48 (2.74)	-1.86 (-9.79, 6.06) 0.643 [-0.07 (-0.48, 0.34)]

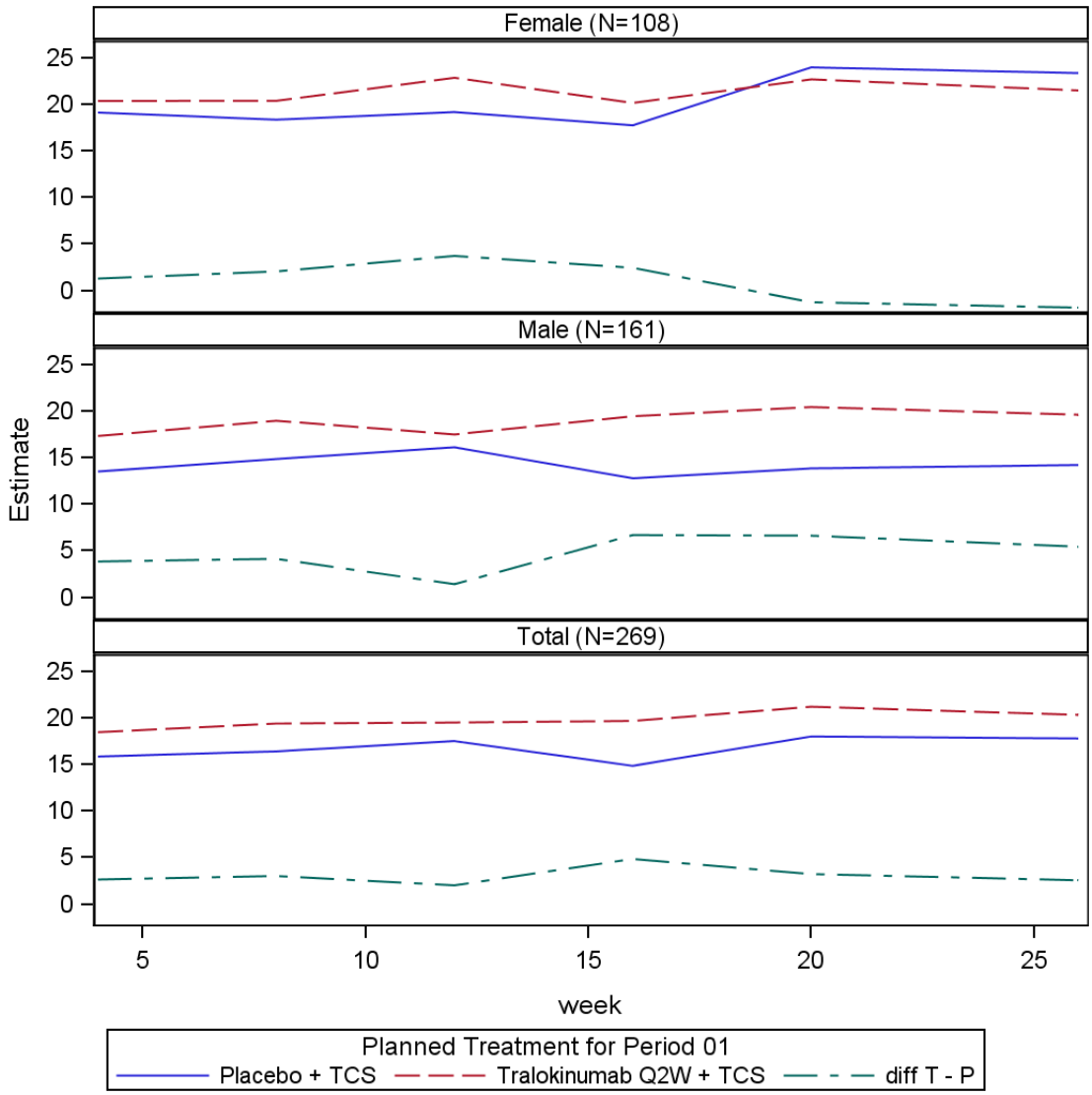
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2785
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.430.4.1: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male										
Baseline	83	81	55.1 (21.74)		81	80	56.4 (19.01)			
Week 4		78	68.9 (16.42)			78	73.4 (17.14)			
Week 4 chg		78	14.1 (20.58)	13.49 (1.77)		78	17.1 (17.13)	17.31 (1.77)	3.82 (-1.11, 8.74) [0.20 (-0.11, 0.52)]	0.128
Week 8		78	70.8 (17.24)			75	75.8 (15.10)			
Week 8 chg		78	15.6 (21.73)	14.84 (1.77)		75	19.3 (18.82)	18.95 (1.79)	4.11 (-0.85, 9.06) [0.20 (-0.12, 0.52)]	0.104
Week 12		75	71.2 (18.38)			73	74.8 (15.36)			
Week 12 chg		75	17.1 (19.08)	16.10 (1.79)		73	17.8 (18.87)	17.48 (1.81)	1.38 (-3.62, 6.38) [0.07 (-0.25, 0.40)]	0.588
Week 16		75	68.4 (20.11)			71	77.1 (15.15)			
Week 16 chg		75	13.9 (24.34)	12.77 (1.78)		71	18.6 (20.48)	19.43 (1.82)	6.66 (1.64, 11.69) [0.30 (-0.03, 0.62)]	0.009
Week 20		62	70.2 (19.22)			64	77.5 (13.32)			
Week 20 chg		62	14.9 (23.69)	13.83 (1.87)		64	21.3 (16.38)	20.42 (1.86)	6.60 (1.40, 11.79) [0.32 (-0.03, 0.68)]	0.013
Week 26		70	69.9 (19.09)			67	76.9 (14.10)			
Week 26 chg		70	15.1 (23.38)	14.19 (1.81)		67	20.3 (17.83)	19.60 (1.84)	5.41 (0.32, 10.50) [0.26 (-0.08, 0.60)]	0.037

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2785
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.4.430.4.2: Total, Gender, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.4.431.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 26		117 2.9 (2.55)			122 2.1 (2.00)		
Week 26 chg		116 -4.0 (2.53)	-3.74 (0.21)		121 -4.1 (2.47)	-4.34 (0.20)	-0.60 (-1.17, -0.03) 0.040 [-0.24 (-0.50, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0102
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.431.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 6.9 (1.84)		57	57 6.7 (2.11)		
Week 26		48 2.2 (2.48)			53 2.4 (2.41)		
Week 26 chg		47 -4.7 (2.49)	-4.55 (0.35)		53 -4.3 (3.01)	-4.35 (0.33)	0.20 (-0.76, 1.17) 0.680 [0.07 (-0.32, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0102
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.431.4.1: Total, Gender, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 6.9 (1.52)		81	80 6.1 (2.08)			
Week 26		69 3.4 (2.47)			69 1.9 (1.61)			
Week 26 chg		69 -3.5 (2.47)	-3.16 (0.24)		68 -4.0 (1.97)	-4.36 (0.24)	-1.20 (-1.89, -0.50) [-0.54 (-0.88, -0.19)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0102
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.434.4.1: Total, Gender, SCORAD 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	21 (15.2)	11.7 (5.02;18.46)	4.3 (1.66;10.96)	5.0 (1.80;13.99)	0.0009	0.3229
Placebo + TCS	137	5 (3.6)					
Female							
Tralokinumab Q2W + TCS	57	8 (14.0)	8.9 (-1.59;19.39)	2.7 (0.76; 9.57)	3.2 (0.76;13.91)	0.1081	
Placebo + TCS	54	3 (5.6)					
Male							
Tralokinumab Q2W + TCS	81	13 (16.0)	13.6 (5.02;22.25)	6.9 (1.55;30.66)	8.0 (1.70;38.02)	0.0027	
Placebo + TCS	83	2 (2.4)					

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. Treatment policy estimand: Missing values at Week 26 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

Table 1.4.437.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss											
Total											
Baseline	137	137	6.7 (2.21)			138	138	6.7 (2.36)			
Week 26		121	2.5 (2.71)				127	1.6 (2.07)			
Week 26 chg		121	-4.4 (3.09)	-4.30	(0.21)		127	-5.0 (2.78)	-5.09	(0.21)	-0.78 (-1.37, -0.20) 0.009 [-0.27 (-0.52, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0151
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.437.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 7.3 (1.97)		57	57 7.1 (2.25)		
Week 26		47 1.9 (2.74)			54 1.8 (2.44)		
Week 26 chg		47 -5.6 (2.93)	-5.41 (0.37)		54 -5.2 (3.24)	-5.40 (0.35)	0.02 (-1.00, 1.03) 0.976 [0.00 (-0.39, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0151
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.437.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 6.4 (2.28)		81	81 6.4 (2.41)			
Week 26		74 2.8 (2.65)			73 1.5 (1.74)			
Week 26 chg		74 -3.6 (2.94)	-3.56 (0.24)		73 -4.8 (2.40)	-4.90 (0.25)	-1.34 (-2.03, -0.65) [-0.50 (-0.83, -0.17)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0151
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.438.4.1: Total, Gender, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score											
Total											
Baseline	137	137	70.8 (12.84)			138	138	70.2 (12.05)			
Week 26		121	33.4 (18.31)				127	24.1 (16.65)			
Week 26 chg		121	-37.9 (19.30)	-37.26	(1.53)		127	-45.9 (19.70)	-46.62	(1.50)	-9.36 (-13.6, -5.13) <.001 [-0.48 (-0.73, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1520
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.438.4.1: Total, Gender, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 72.0 (13.89)		57	57 71.2 (11.89)		
Week 26		47 30.5 (18.93)			54 25.8 (16.22)		
Week 26 chg		47 -41.9 (21.40)	-41.15 (2.44)		54 -45.3 (19.68)	-45.88 (2.28)	-4.73 (-11.4, 1.90) 0.160 [-0.23 (-0.62, 0.16)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1520
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.438.4.1: Total, Gender, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	83 70.0 (12.13)		81	81 69.5 (12.18)			
Week 26		74 35.2 (17.79)			73 22.8 (16.96)			
Week 26 chg		74 -35.3 (17.51)	-34.75 (1.95)		73 -46.4 (19.84)	-47.24 (1.96)	-12.49 (-18.0, -7.01) [-0.67 (-1.00, -0.34)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1520
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.439.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)										
Total										
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)			
Week 26		117	3.9 (2.53)			122	3.0 (1.94)			
Week 26 chg		116	-3.6 (2.55)	-3.47 (0.20)		121	-4.2 (2.13)	-4.31 (0.20)	-0.84 (-1.41, -0.28) [-0.36 (-0.62, -0.10)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0654
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.439.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 7.7 (1.40)		57	57 7.6 (1.42)		
Week 26		48 3.4 (2.57)			53 3.2 (2.29)		
Week 26 chg		47 -4.2 (2.82)	-4.17 (0.36)		53 -4.5 (2.52)	-4.48 (0.33)	-0.31 (-1.28, 0.66) 0.521 [-0.12 (-0.51, 0.27)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0654
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.439.4.1: Total, Gender, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 7.3 (1.34)		81	80 7.0 (1.43)		
Week 26		69 4.3 (2.45)			69 2.9 (1.64)		
Week 26 chg		69 -3.1 (2.27)	-2.98 (0.24)		68 -4.1 (1.76)	-4.19 (0.24)	-1.21 (-1.88, -0.53) <.001 [-0.59 (-0.93, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0654
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.440.4.1: Total, Gender, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total							
Total							
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)		
Week 26		115 11.9 (7.89)			119 8.4 (5.90)		
Week 26 chg		113 -8.7 (8.23)	-8.90 (0.62)		116 -12.7 (6.64)	-12.63 (0.62)	-3.73 (-5.46, -2.00) <.001 [-0.50 (-0.76, -0.24)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2548
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.440.4.1: Total, Gender, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 21.2 (5.64)		57	55 21.7 (5.28)		
Week 26		44 11.6 (7.87)			51 9.7 (6.24)		
Week 26 chg		43 -9.7 (8.54)	-9.92 (1.07)		49 -12.1 (7.25)	-11.94 (1.00)	-2.03 (-4.95, 0.90) 0.172 [-0.26 (-0.67, 0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2548
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.440.4.1: Total, Gender, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	81 20.6 (5.80)		81	80 21.0 (5.02)		
Week 26		71 12.1 (7.95)			68 7.5 (5.48)		
Week 26 chg		70 -8.1 (8.04)	-8.26 (0.77)		67 -13.2 (6.16)	-13.17 (0.79)	-4.91 (-7.08, -2.74) <.001 [-0.68 (-1.03, -0.34)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2548
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.442.4.1: Total, Gender, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score									
Total									
Baseline	137	134	16.4 (6.33)		138	137	15.9 (6.53)		
Week 26		115	6.2 (5.20)			119	4.4 (4.42)		
Week 26 chg		113	-10.3 (6.57)	-10.01 (0.42)		118	-11.2 (6.17)	-11.51 (0.41)	-1.50 (-2.66, -0.34) 0.011 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1577
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.442.4.1: Total, Gender, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 17.2 (6.62)		57	57 17.1 (6.83)		
Week 26		44 5.6 (5.47)			51 4.8 (5.16)		
Week 26 chg		43 -12.3 (6.74)	-12.04 (0.76)		51 -12.4 (6.79)	-12.60 (0.70)	-0.56 (-2.61, 1.49) 0.591 [-0.08 (-0.49, 0.32)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1577
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.442.4.1: Total, Gender, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	81 15.8 (6.11)		81	80 15.0 (6.22)			
Week 26		71 6.6 (5.03)			68 4.1 (3.79)			
Week 26 chg		70 -9.1 (6.22)	-8.69 (0.49)		67 -10.2 (5.52)	-10.76 (0.50)	-2.06 (-3.46, -0.66) [-0.35 (-0.69, -0.01)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1577
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.443.4.1: Total, Gender, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score									
Total									
Baseline	137	137	33.8 (13.46)		138	138	32.1 (11.53)		
Week 26		121	9.0 (10.05)			127	5.8 (7.95)		
Week 26 chg		121	-25.4 (13.63)	-24.33 (0.78)		127	-26.3 (12.87)	-27.34 (0.76)	-3.02 (-5.16, -0.87) 0.006 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2571
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.443.4.1: Total, Gender, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 33.2 (14.65)		57	57 33.2 (12.33)		
Week 26		47 7.5 (9.17)			54 5.6 (6.32)		
Week 26 chg		47 -25.9 (16.09)	-25.71 (1.09)		54 -27.5 (12.79)	-27.68 (1.02)	-1.97 (-4.94, 1.01) 0.192 [-0.14 (-0.53, 0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2571
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.443.4.1: Total, Gender, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 34.3 (12.71)		81	81 31.3 (10.94)		
Week 26		74 10.0 (10.52)			73 5.9 (9.01)		
Week 26 chg		74 -25.0 (11.92)	-23.54 (1.05)		73 -25.4 (12.93)	-27.04 (1.07)	-3.50 (-6.50, -0.51) 0.022 [-0.28 (-0.61, 0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2571
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.444.3.1: Total, Gender, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	126	126 30.4 (12.78)		252	252 28.8 (11.97)		
Week 16		123 14.1 (14.89)			241 8.1 (9.15)		
Week 16 chg		123 -16.0 (14.04)	-15.43 (0.94)		241 -20.7 (12.33)	-20.93 (0.67)	-5.50 (-7.79, -3.22) <.001 [-0.43 (-0.64, -0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0367
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.444.3.1: Total, Gender, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	43	43 26.8 (10.17)		127	127 27.0 (10.83)		
Week 16		42 10.2 (11.20)			122 6.3 (7.44)		
Week 16 chg		42 -16.0 (10.95)	-16.48 (1.25)		122 -20.7 (11.33)	-20.52 (0.73)	-4.04 (-6.92, -1.16) 0.006 [-0.36 (-0.71, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0367
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.444.3.1: Total, Gender, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 32.3 (13.63)		125	125 30.6 (12.81)		
Week 16		81 16.1 (16.19)			119 9.9 (10.34)		
Week 16 chg		81 -16.0 (15.46)	-15.43 (1.33)		119 -20.6 (13.33)	-20.97 (1.10)	-5.54 (-8.95, -2.14) 0.002 [-0.39 (-0.67, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0367
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.4.445.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.39 (0.22)		138 -2.8 (2.87)	-2.85 (0.22)	-0.46 (-1.07, 0.15) 0.140 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.20 (0.22)		137 -3.8 (2.99)	-3.79 (0.22)	-0.58 (-1.20, 0.03) 0.062 [-0.19 (-0.42, 0.05)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.13 (0.22)		134 -4.1 (2.81)	-4.06 (0.22)	-0.93 (-1.54, -0.31) 0.003 [-0.30 (-0.54, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.47 (0.22)		130 -4.4 (2.91)	-4.33 (0.22)	-0.85 (-1.47, -0.24) 0.007 [-0.27 (-0.52, -0.03)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.62 (0.22)		130 -4.5 (2.93)	-4.44 (0.22)	-0.82 (-1.43, -0.20) 0.009 [-0.26 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.70 (0.22)		128 -4.6 (2.96)	-4.53 (0.22)	-0.83 (-1.45, -0.21) 0.008 [-0.26 (-0.51, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2905
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.4.445.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	2.8 (2.94)		127	2.3 (2.60)		
Week 14 chg	126	-4.0 (3.48)	-3.86 (0.22)	127	-4.4 (3.07)	-4.31 (0.22)	-0.45 (-1.07, 0.17) 0.156 [-0.14 (-0.38, 0.11)]
Week 16	124	2.7 (2.77)		123	1.9 (2.39)		
Week 16 chg	124	-4.1 (3.25)	-3.91 (0.22)	123	-4.7 (2.92)	-4.63 (0.22)	-0.72 (-1.34, -0.10) 0.024 [-0.23 (-0.48, 0.02)]
Week 18	116	2.9 (2.83)		115	1.7 (2.27)		
Week 18 chg	116	-3.9 (3.35)	-3.71 (0.23)	115	-4.8 (2.93)	-4.81 (0.23)	-1.10 (-1.73, -0.47) <.001 [-0.35 (-0.61, -0.09)]
Week 20	107	2.6 (2.71)		117	1.8 (2.37)		
Week 20 chg	107	-4.1 (3.17)	-3.95 (0.23)	117	-4.8 (2.97)	-4.78 (0.23)	-0.83 (-1.46, -0.20) 0.010 [-0.27 (-0.53, -0.01)]
Week 22	112	2.5 (2.71)		114	1.5 (2.00)		
Week 22 chg	112	-4.2 (3.34)	-4.07 (0.23)	114	-5.0 (2.85)	-4.94 (0.23)	-0.87 (-1.51, -0.24) 0.007 [-0.28 (-0.54, -0.02)]
Week 24	112	2.3 (2.55)		117	1.5 (2.05)		
Week 24 chg	112	-4.4 (3.18)	-4.21 (0.23)	117	-5.1 (2.80)	-4.96 (0.23)	-0.76 (-1.39, -0.12) 0.019 [-0.25 (-0.51, 0.01)]
Week 26	118	2.4 (2.70)		125	1.6 (2.07)		
Week 26 chg	118	-4.4 (3.11)	-4.20 (0.23)	125	-5.0 (2.80)	-4.92 (0.22)	-0.72 (-1.35, -0.10) 0.024 [-0.24 (-0.50, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2905
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.4.445.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 7.3 (1.97)		57	57 7.1 (2.25)		
Week 2		54 4.2 (3.12)			57 4.2 (2.80)		
Week 2 chg		54 -3.1 (2.99)	-3.04 (0.38)		57 -2.9 (2.92)	-2.95 (0.37)	0.09 (-0.95, 1.13) 0.864 [0.03 (-0.34, 0.40)]
Week 4		53 3.1 (2.91)			57 3.2 (2.97)		
Week 4 chg		53 -4.2 (3.10)	-4.06 (0.38)		57 -3.9 (3.32)	-4.00 (0.37)	0.06 (-0.98, 1.10) 0.906 [0.02 (-0.35, 0.39)]
Week 6		52 3.3 (2.98)			56 2.8 (2.80)		
Week 6 chg		52 -4.1 (3.19)	-3.94 (0.38)		56 -4.3 (3.01)	-4.40 (0.37)	-0.47 (-1.51, 0.58) 0.379 [-0.15 (-0.53, 0.23)]
Week 8		52 2.9 (2.81)			54 2.4 (2.62)		
Week 8 chg		52 -4.5 (3.12)	-4.34 (0.38)		54 -4.7 (2.99)	-4.77 (0.37)	-0.44 (-1.49, 0.61) 0.411 [-0.14 (-0.52, 0.24)]
Week 10		52 2.8 (2.92)			54 2.3 (2.73)		
Week 10 chg		52 -4.6 (3.19)	-4.43 (0.38)		54 -4.8 (3.09)	-4.89 (0.37)	-0.46 (-1.50, 0.59) 0.390 [-0.15 (-0.53, 0.24)]
Week 12		51 2.5 (2.80)			53 2.2 (2.80)		
Week 12 chg		51 -4.9 (3.27)	-4.70 (0.38)		53 -5.0 (3.16)	-5.05 (0.37)	-0.35 (-1.40, 0.70) 0.512 [-0.11 (-0.49, 0.28)]
Week 14		51 2.4 (3.02)			53 2.3 (2.97)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2905
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.4.445.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	51	-5.0 (3.24)	-4.86 (0.38)	53	-4.8 (3.38)	-4.83 (0.37)	0.04 (-1.01, 1.09) 0.946 [0.01 (-0.37, 0.40)]
Week 16	48	1.9 (2.50)		50	2.1 (2.82)		
Week 16 chg	48	-5.5 (2.86)	-5.18 (0.38)	50	-4.9 (3.30)	-5.06 (0.37)	0.12 (-0.94, 1.18) 0.822 [0.04 (-0.36, 0.44)]
Week 18	46	2.2 (2.85)		48	1.9 (2.79)		
Week 18 chg	46	-5.2 (3.08)	-4.95 (0.39)	48	-5.2 (3.25)	-5.23 (0.38)	-0.28 (-1.34, 0.79) 0.611 [-0.09 (-0.49, 0.32)]
Week 20	44	2.2 (3.05)		48	2.1 (2.88)		
Week 20 chg	44	-5.1 (3.11)	-4.97 (0.39)	48	-4.9 (3.39)	-4.96 (0.38)	0.01 (-1.06, 1.08) 0.984 [0.00 (-0.41, 0.41)]
Week 22	42	1.6 (2.51)		47	1.7 (2.47)		
Week 22 chg	42	-5.6 (3.02)	-5.23 (0.39)	47	-5.3 (3.31)	-5.21 (0.38)	0.02 (-1.06, 1.10) 0.966 [0.01 (-0.41, 0.42)]
Week 24	43	1.7 (2.43)		48	1.8 (2.70)		
Week 24 chg	43	-5.6 (3.12)	-5.12 (0.39)	48	-5.2 (3.38)	-5.11 (0.38)	0.01 (-1.06, 1.09) 0.982 [0.00 (-0.41, 0.42)]
Week 26	46	1.8 (2.76)		52	1.8 (2.47)		
Week 26 chg	46	-5.7 (2.95)	-5.19 (0.39)	52	-5.2 (3.30)	-5.27 (0.37)	-0.08 (-1.14, 0.98) 0.881 [-0.03 (-0.42, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2905
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

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Table 1.4.445.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 6.4 (2.28)		81	81 6.4 (2.41)		
Week 2		83 4.4 (2.50)			81 3.6 (2.64)		
Week 2 chg		83 -2.0 (2.92)	-1.96 (0.26)		81 -2.8 (2.84)	-2.80 (0.27)	-0.85 (-1.59, -0.11) 0.025 [-0.29 (-0.60, 0.01)]
Week 4		81 3.6 (2.64)			80 2.6 (2.45)		
Week 4 chg		81 -2.7 (3.30)	-2.62 (0.27)		80 -3.7 (2.74)	-3.67 (0.27)	-1.05 (-1.79, -0.30) 0.006 [-0.34 (-0.66, -0.03)]
Week 6		80 3.7 (2.83)			78 2.4 (2.41)		
Week 6 chg		80 -2.7 (3.27)	-2.57 (0.27)		78 -3.9 (2.67)	-3.83 (0.27)	-1.26 (-2.01, -0.52) <.001 [-0.42 (-0.74, -0.11)]
Week 8		81 3.4 (2.61)			76 2.2 (2.37)		
Week 8 chg		81 -3.0 (3.27)	-2.89 (0.27)		76 -4.2 (2.86)	-4.03 (0.27)	-1.15 (-1.90, -0.40) 0.003 [-0.37 (-0.69, -0.06)]
Week 10		79 3.2 (2.69)			76 2.1 (2.44)		
Week 10 chg		79 -3.2 (3.40)	-3.06 (0.27)		76 -4.2 (2.80)	-4.14 (0.27)	-1.08 (-1.83, -0.33) 0.005 [-0.35 (-0.66, -0.03)]
Week 12		77 3.2 (2.58)			75 2.1 (2.25)		
Week 12 chg		77 -3.2 (3.27)	-3.02 (0.27)		75 -4.3 (2.81)	-4.20 (0.27)	-1.18 (-1.93, -0.42) 0.002 [-0.39 (-0.71, -0.06)]
Week 14		75 3.0 (2.88)			74 2.3 (2.31)		

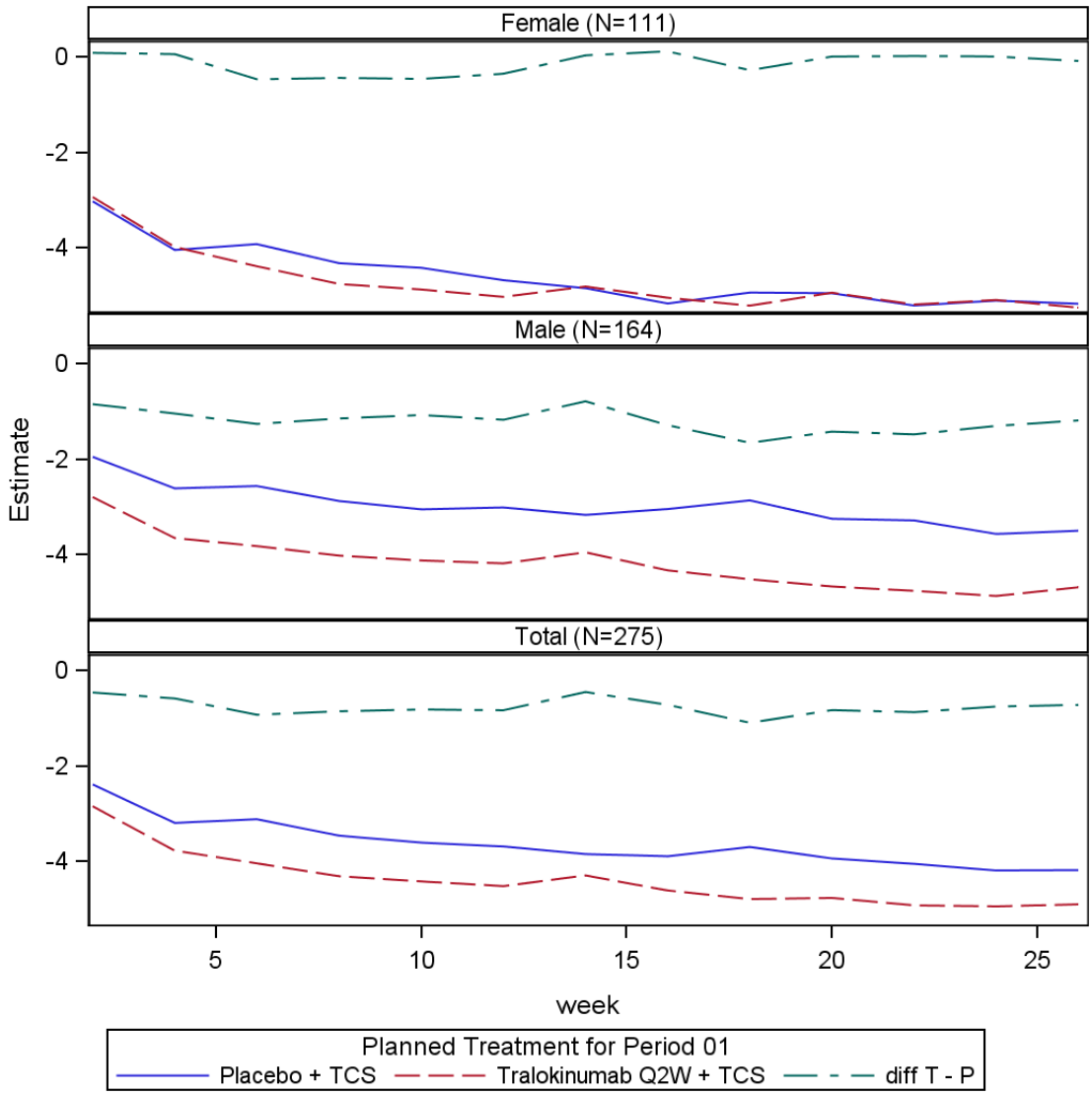
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2905
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.4.445.4.1: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	75	-3.4 (3.50)	-3.18 (0.27)	74	-4.1 (2.81)	-3.97 (0.27)	-0.79 (-1.54, -0.03) [-0.25 (-0.57, 0.07)]	0.041
Week 16	76	3.2 (2.82)		73	1.8 (2.07)			
Week 16 chg	76	-3.2 (3.20)	-3.05 (0.27)	73	-4.5 (2.64)	-4.35 (0.27)	-1.29 (-2.05, -0.54) [-0.44 (-0.76, -0.11)]	<.001
Week 18	70	3.4 (2.73)		67	1.5 (1.82)			
Week 18 chg	70	-3.0 (3.27)	-2.87 (0.27)	67	-4.5 (2.67)	-4.53 (0.28)	-1.66 (-2.43, -0.89) [-0.56 (-0.90, -0.21)]	<.001
Week 20	63	2.9 (2.43)		69	1.5 (1.92)			
Week 20 chg	63	-3.5 (3.07)	-3.26 (0.28)	69	-4.7 (2.67)	-4.68 (0.28)	-1.43 (-2.20, -0.65) [-0.50 (-0.84, -0.15)]	<.001
Week 22	70	2.9 (2.72)		67	1.3 (1.59)			
Week 22 chg	70	-3.4 (3.28)	-3.29 (0.27)	67	-4.8 (2.48)	-4.78 (0.28)	-1.48 (-2.25, -0.72) [-0.51 (-0.85, -0.17)]	<.001
Week 24	69	2.6 (2.58)		69	1.3 (1.40)			
Week 24 chg	69	-3.7 (3.03)	-3.58 (0.27)	69	-5.0 (2.34)	-4.88 (0.28)	-1.31 (-2.07, -0.54) [-0.48 (-0.82, -0.14)]	<.001
Week 26	72	2.8 (2.61)		73	1.5 (1.74)			
Week 26 chg	72	-3.6 (2.95)	-3.51 (0.27)	73	-4.8 (2.40)	-4.70 (0.27)	-1.19 (-1.95, -0.43) [-0.44 (-0.77, -0.11)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2905
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.4.445.4.2: Total, Gender, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.4.446.4.1: Total, Gender, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.89 (0.84)		123 -25.9 (12.78)	-26.75 (0.84)	-3.86 (-6.21, -1.51) 0.001 [-0.28 (-0.53, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3042
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.446.4.1: Total, Gender, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	54 33.2 (14.65)		57	57 33.2 (12.33)		
Week 16		48 9.5 (12.99)			50 5.6 (7.06)		
Week 16 chg		48 -24.6 (17.73)	-24.47 (1.47)		50 -28.1 (13.46)	-28.28 (1.43)	-3.81 (-7.88, 0.26) 0.066 [-0.24 (-0.64, 0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3042
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.446.4.1: Total, Gender, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	83 34.3 (12.71)		81	81 31.3 (10.94)		
Week 16		76 11.2 (10.34)			73 6.9 (8.01)		
Week 16 chg		76 -23.3 (12.96)	-21.96 (1.01)		73 -24.3 (12.14)	-25.63 (1.04)	-3.67 (-6.57, -0.78) 0.013 [-0.29 (-0.62, 0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3042
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.463.4.1: Total, Gender, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary									
Total									
Baseline	137	134	44.5 (8.19)		138	134	44.5 (7.83)		
Week 8		129	50.3 (7.06)			129	51.7 (7.07)		
Week 8 chg		129	5.6 (7.75)	5.69 (0.56)		129	7.4 (7.27)	7.16 (0.56)	1.47 (-0.08, 3.03) 0.063 [0.20 (-0.05, 0.44)]
Week 16		119	50.9 (7.78)			113	52.9 (6.85)		
Week 16 chg		119	6.8 (8.15)	6.49 (0.57)		113	8.0 (7.67)	7.87 (0.58)	1.39 (-0.22, 2.99) 0.090 [0.17 (-0.08, 0.43)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0168
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.463.4.1: Total, Gender, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	54	53 44.5 (8.34)		57	55 44.2 (8.08)			
Week 8		51 49.7 (7.58)			52 51.7 (7.53)			
Week 8 chg		51 4.9 (8.90)	5.37 (1.04)		52 7.6 (8.04)	7.17 (1.02)	1.80 (-1.08, 4.69) [0.21 (-0.17, 0.60)]	0.219
Week 16		44 52.6 (7.65)			43 52.4 (8.42)			
Week 16 chg		44 8.5 (10.08)	8.20 (1.07)		43 8.2 (9.54)	8.15 (1.06)	-0.05 (-3.03, 2.93) [-0.01 (-0.43, 0.42)]	0.973

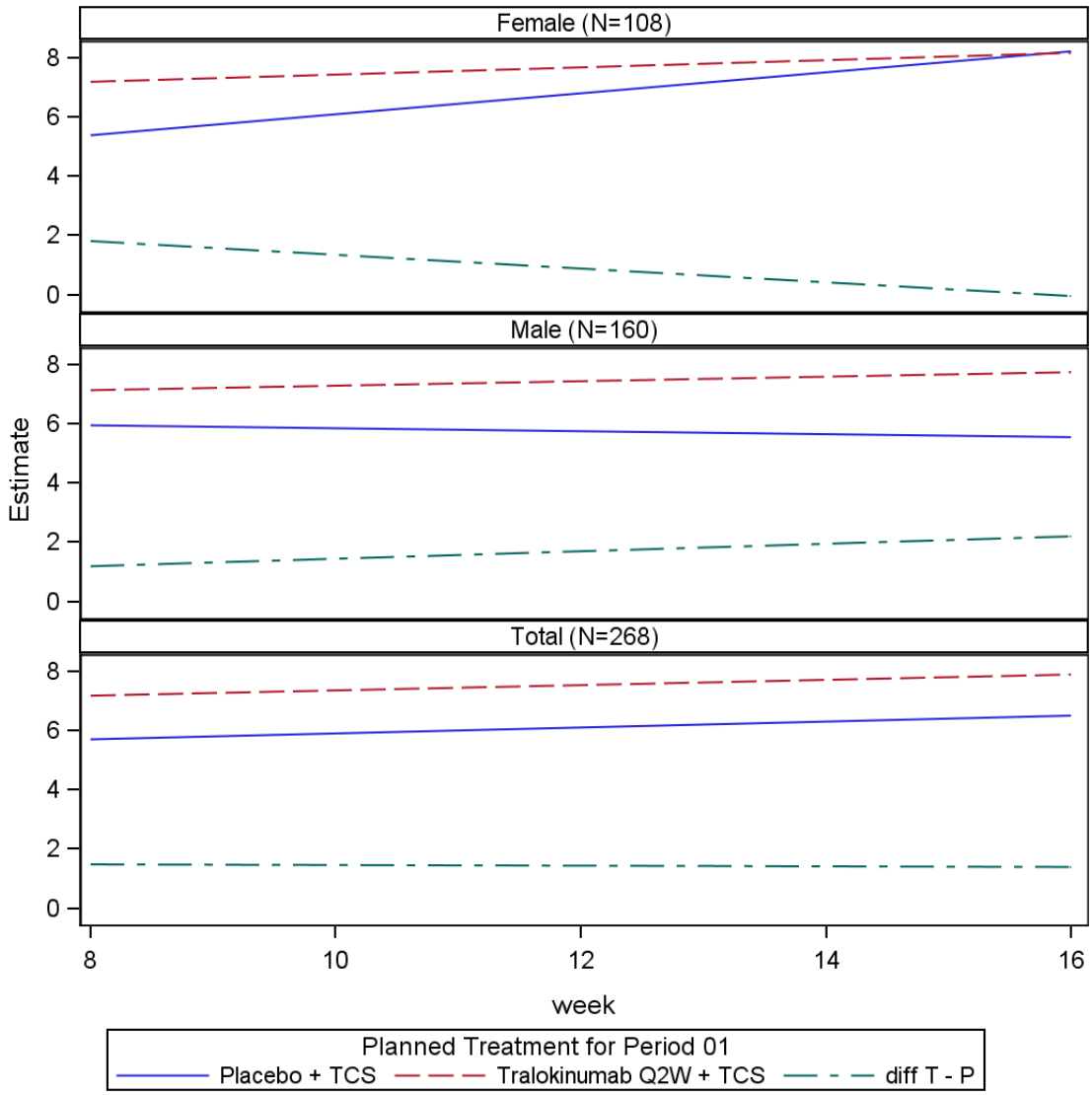
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0168
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.463.4.1: Total, Gender, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	81 44.5 (8.15)		81	79 44.8 (7.70)			
Week 8		78 50.6 (6.73)			77 51.7 (6.80)			
Week 8 chg		78 6.0 (6.92)	5.93 (0.62)		77 7.2 (6.75)	7.12 (0.63)	1.18 (-0.56, 2.92) [0.17 (-0.14, 0.49)]	0.182
Week 16		75 50.0 (7.75)			70 53.1 (5.72)			
Week 16 chg		75 5.8 (6.66)	5.54 (0.63)		70 7.8 (6.33)	7.73 (0.65)	2.19 (0.40, 3.98) [0.34 (0.01, 0.66)]	0.017

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0168
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.463.4.2: Total, Gender, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, 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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.464.4.1: Total, Gender, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Mental component summary										
Total										
Baseline	137	134	44.9 (11.42)		138	134	46.3 (9.74)			
Week 8		129	49.6 (10.25)			129	49.7 (9.51)			
Week 8 chg		129	4.4 (7.37)	4.13 (0.64)		129	3.7 (8.69)	3.69 (0.63)	-0.44 (-2.21, 1.33) [-0.05 (-0.30, 0.19)]	0.625
Week 16		119	49.5 (10.11)			113	49.9 (9.68)			
Week 16 chg		119	4.4 (8.65)	4.08 (0.65)		113	3.4 (8.59)	3.59 (0.66)	-0.50 (-2.32, 1.33) [-0.06 (-0.32, 0.20)]	0.594
Week 26		110	50.4 (9.75)			112	51.4 (7.72)			
Week 26 chg		110	5.5 (8.68)	4.92 (0.67)		112	4.6 (8.26)	4.50 (0.66)	-0.42 (-2.27, 1.44) [-0.05 (-0.31, 0.21)]	0.660

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.464.4.1: Total, Gender, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 41.5 (12.42)		57	55 45.5 (9.37)		
Week 8		51 47.4 (10.87)			52 49.1 (8.32)		
Week 8 chg		51 5.8 (8.28)	4.71 (1.10)		52 3.9 (9.06)	4.48 (1.08)	-0.23 (-3.30, 2.84) 0.883 [-0.03 (-0.41, 0.36)]
Week 16		44 48.4 (11.12)			43 47.6 (11.58)		
Week 16 chg		44 6.2 (9.25)	5.48 (1.15)		43 2.0 (9.99)	2.55 (1.15)	-2.94 (-6.16, 0.29) 0.074 [-0.31 (-0.73, 0.12)]
Week 26		42 48.7 (10.62)			47 50.7 (7.78)		
Week 26 chg		42 7.4 (9.82)	5.99 (1.17)		47 4.7 (8.34)	5.39 (1.12)	-0.60 (-3.83, 2.64) 0.717 [-0.07 (-0.48, 0.35)]

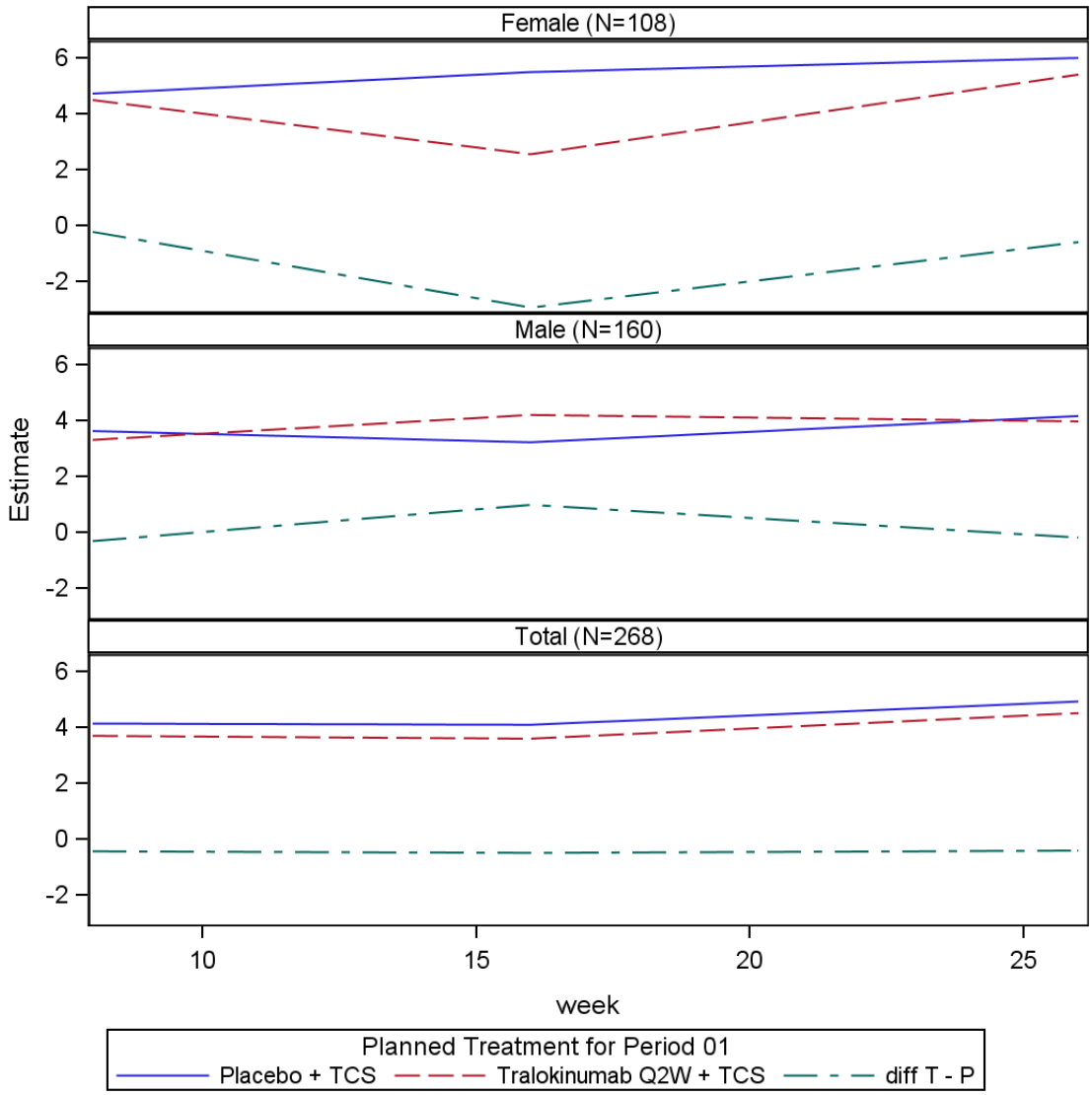
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.464.4.1: Total, Gender, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	81 47.1 (10.20)		81	79 46.8 (10.02)			
Week 8		78 51.0 (9.62)			77 50.0 (10.27)			
Week 8 chg		78 3.5 (6.61)	3.62 (0.77)		77 3.5 (8.48)	3.30 (0.78)	-0.32 (-2.47, 1.84) [-0.04 (-0.36, 0.27)]	0.772
Week 16		75 50.2 (9.48)			70 51.4 (8.06)			
Week 16 chg		75 3.3 (8.14)	3.22 (0.78)		70 4.3 (7.56)	4.19 (0.80)	0.98 (-1.22, 3.18) [0.12 (-0.20, 0.45)]	0.381
Week 26		68 51.5 (9.10)			65 51.8 (7.70)			
Week 26 chg		68 4.3 (7.71)	4.15 (0.80)		65 4.5 (8.27)	3.96 (0.82)	-0.19 (-2.44, 2.06) [-0.02 (-0.36, 0.32)]	0.868

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.464.4.2: Total, Gender, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.465.4.1: Total, Gender, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary									
Total									
Baseline	137	134	44.5 (8.19)		138	134	44.5 (7.83)		
Week 8		129	50.3 (7.06)			129	51.7 (7.07)		
Week 8 chg		129	5.6 (7.75)	5.70 (0.56)		129	7.4 (7.27)	7.18 (0.56)	1.48 (-0.09, 3.04) 0.064 [0.20 (-0.05, 0.44)]
Week 16		119	50.9 (7.78)			113	52.9 (6.85)		
Week 16 chg		119	6.8 (8.15)	6.57 (0.57)		113	8.0 (7.67)	7.95 (0.58)	1.37 (-0.23, 2.98) 0.093 [0.17 (-0.08, 0.43)]
Week 26		110	50.7 (7.62)			112	52.9 (7.40)		
Week 26 chg		110	6.9 (8.19)	6.11 (0.59)		112	8.2 (7.71)	8.22 (0.58)	2.11 (0.48, 3.74) 0.011 [0.27 (0.00, 0.53)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0278
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.465.4.1: Total, Gender, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female									
Baseline	54	53	44.5 (8.34)		57	55	44.2 (8.08)		
Week 8		51	49.7 (7.58)			52	51.7 (7.53)		
Week 8 chg		51	4.9 (8.90)	5.38 (1.03)		52	7.6 (8.04)	7.17 (1.02)	1.79 (-1.08, 4.66) 0.220 [0.21 (-0.18, 0.60)]
Week 16		44	52.6 (7.65)			43	52.4 (8.42)		
Week 16 chg		44	8.5 (10.08)	8.28 (1.06)		43	8.2 (9.54)	8.28 (1.05)	-0.00 (-2.96, 2.96) 0.998 [-0.00 (-0.42, 0.42)]
Week 26		42	52.5 (7.39)			47	52.5 (8.88)		
Week 26 chg		42	8.7 (8.97)	7.28 (1.07)		47	8.1 (9.35)	8.51 (1.04)	1.23 (-1.72, 4.18) 0.411 [0.13 (-0.28, 0.55)]

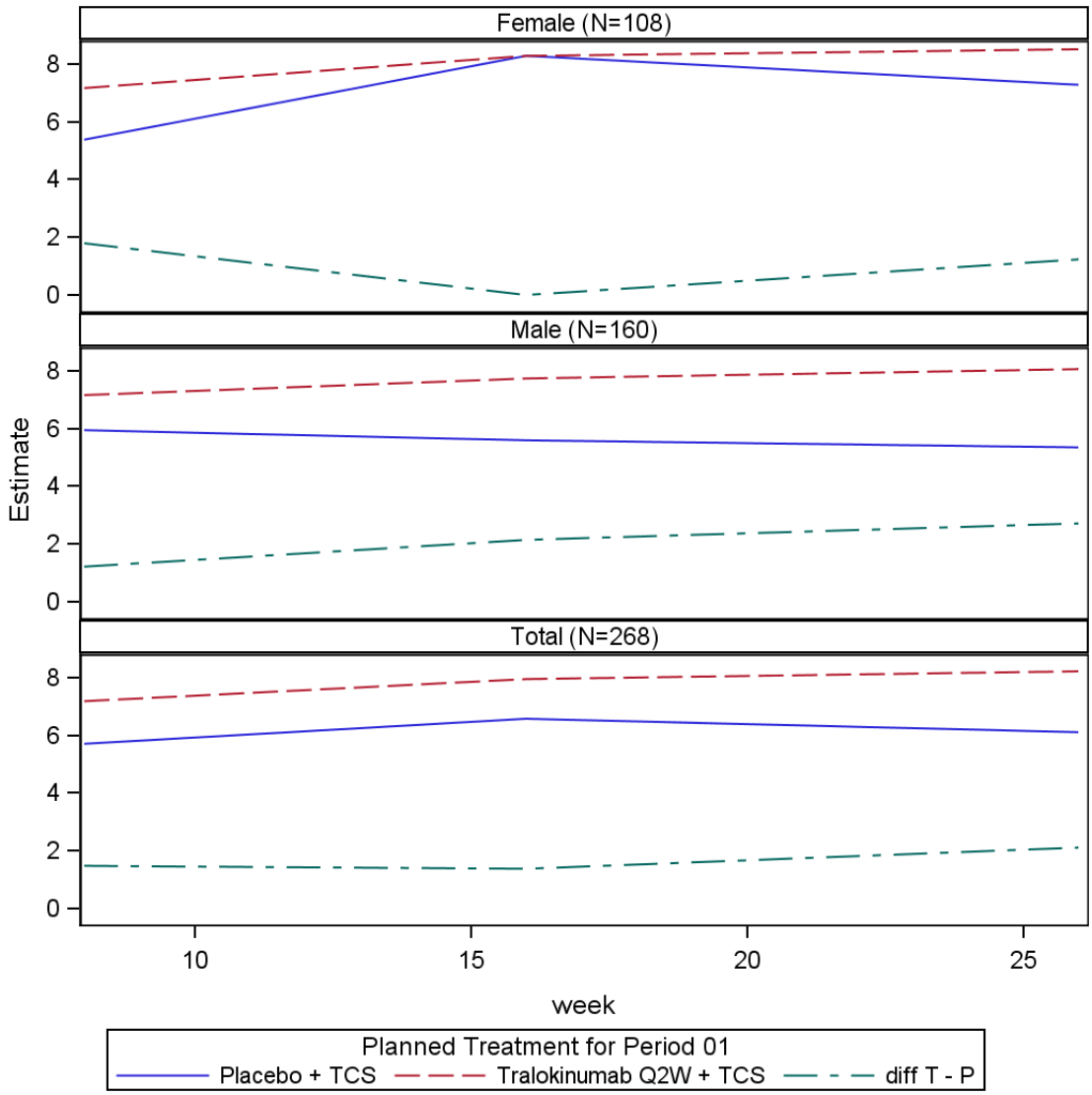
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0278
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.465.4.1: Total, Gender, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male							
Baseline	83	81 44.5 (8.15)		81	79 44.8 (7.70)		
Week 8		78 50.6 (6.73)			77 51.7 (6.80)		
Week 8 chg		78 6.0 (6.92)	5.94 (0.63)		77 7.2 (6.75)	7.16 (0.64)	1.22 (-0.55, 2.98) 0.177 [0.18 (-0.14, 0.49)]
Week 16		75 50.0 (7.75)			70 53.1 (5.72)		
Week 16 chg		75 5.8 (6.66)	5.59 (0.64)		70 7.8 (6.33)	7.73 (0.66)	2.14 (0.33, 3.95) 0.021 [0.33 (0.00, 0.66)]
Week 26		68 49.7 (7.62)			65 53.2 (6.17)		
Week 26 chg		68 5.7 (7.51)	5.35 (0.66)		65 8.3 (6.34)	8.06 (0.67)	2.71 (0.85, 4.57) 0.004 [0.39 (0.05, 0.73)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0278
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.465.4.2: Total, Gender, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.466.4.1: Total, Gender, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary							
Total							
Baseline	137	134 44.9 (11.42)		138	134 46.3 (9.74)		
Week 8		129 49.6 (10.25)			129 49.7 (9.51)		
Week 8 chg		129 4.4 (7.37)	4.14 (0.65)		129 3.7 (8.69)	3.66 (0.65)	-0.47 (-2.28, 1.34) 0.607 [-0.06 (-0.30, 0.19)]
Week 16		119 49.5 (10.11)			113 49.9 (9.68)		
Week 16 chg		119 4.4 (8.65)	4.09 (0.67)		113 3.4 (8.59)	3.63 (0.68)	-0.46 (-2.34, 1.42) 0.629 [-0.05 (-0.31, 0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2036
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.466.4.1: Total, Gender, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Female								
Baseline	54	53 41.5 (12.42)		57	55 45.5 (9.37)			
Week 8		51 47.4 (10.87)			52 49.1 (8.32)			
Week 8 chg		51 5.8 (8.28)	4.71 (1.15)		52 3.9 (9.06)	4.34 (1.13)	-0.37 (-3.58, 2.83) [-0.04 (-0.43, 0.34)]	0.818
Week 16		44 48.4 (11.12)			43 47.6 (11.58)			
Week 16 chg		44 6.2 (9.25)	5.48 (1.20)		43 2.0 (9.99)	2.65 (1.20)	-2.82 (-6.20, 0.55) [-0.29 (-0.72, 0.13)]	0.100

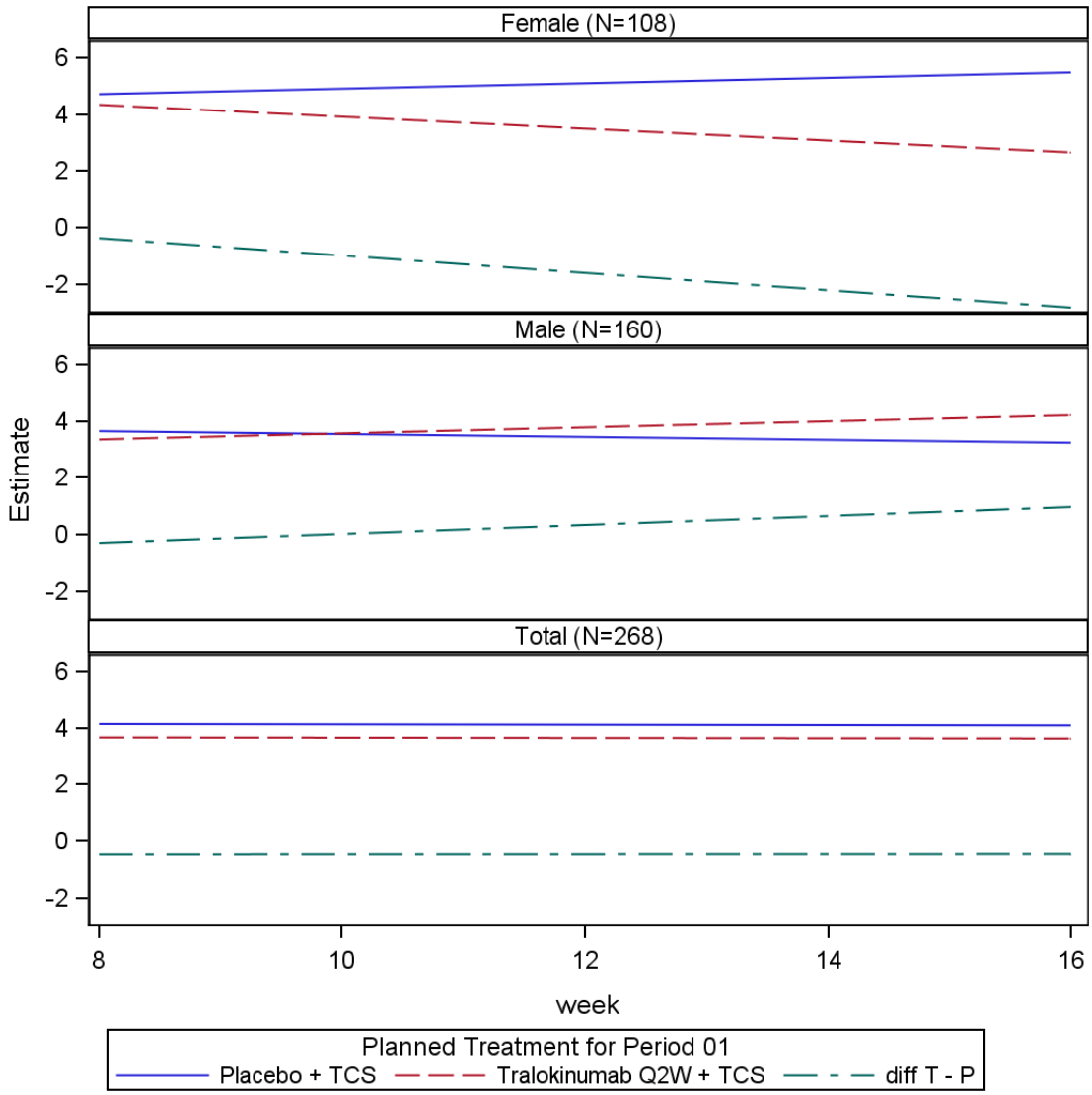
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2036
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.466.4.1: Total, Gender, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	81 47.1 (10.20)		81	79 46.8 (10.02)			
Week 8		78 51.0 (9.62)			77 50.0 (10.27)			
Week 8 chg		78 3.5 (6.61)	3.64 (0.78)		77 3.5 (8.48)	3.35 (0.78)	-0.29 (-2.46, 1.88) [-0.04 (-0.35, 0.28)]	0.791
Week 16		75 50.2 (9.48)			70 51.4 (8.06)			
Week 16 chg		75 3.3 (8.14)	3.24 (0.79)		70 4.3 (7.56)	4.21 (0.81)	0.97 (-1.25, 3.19) [0.12 (-0.20, 0.45)]	0.391

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2036
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.466.4.2: Total, Gender, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, 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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.4.469.4.1: Total, Gender, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 26		115	50.7 (9.70)				118	51.1 (7.88)			
Week 26 chg		113	5.6 (8.87)	5.14	(0.66)		114	4.4 (8.31)	4.80	(0.66)	-0.34 (-2.18, 1.50) 0.715 [-0.04 (-0.30, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8052
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.469.4.1: Total, Gender, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 41.5 (12.42)		57	55 45.5 (9.37)		
Week 26		44 48.8 (10.46)			51 50.1 (8.20)		
Week 26 chg		43 7.9 (10.26)	6.27 (1.16)		49 4.2 (8.46)	5.68 (1.08)	-0.59 (-3.79, 2.62) 0.717 [-0.06 (-0.47, 0.35)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8052
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.469.4.1: Total, Gender, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male											
Baseline	83	81	47.1 (10.20)			81	79	46.8 (10.02)			
Week 26		71	51.8 (9.09)				67	51.9 (7.59)			
Week 26 chg		70	4.2 (7.62)	4.28	(0.80)		65	4.5 (8.27)	4.39	(0.83)	0.11 (-2.16, 2.37) 0.926 [0.01 (-0.32, 0.35)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8052
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.470.4.1: Total, Gender, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary							
Total							
Baseline	137	134 44.5 (8.19)		138	134 44.5 (7.83)		
Week 26		115 50.9 (7.60)			118 52.8 (7.38)		
Week 26 chg		113 6.8 (8.15)	6.63 (0.62)		114 8.4 (7.77)	8.47 (0.62)	1.84 (0.11, 3.56) 0.037 [0.23 (-0.03, 0.49)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0561
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.470.4.1: Total, Gender, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 44.5 (8.34)		57	55 44.2 (8.08)		
Week 26		44 52.7 (7.31)			51 52.2 (8.78)		
Week 26 chg		43 8.7 (8.88)	8.67 (1.16)		49 8.4 (9.40)	8.47 (1.09)	-0.20 (-3.37, 2.98) 0.902 [-0.02 (-0.43, 0.39)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0561
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.470.4.1: Total, Gender, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	81 44.5 (8.15)		81	79 44.8 (7.70)			
Week 26		71 49.8 (7.63)			67 53.2 (6.14)			
Week 26 chg		70 5.5 (7.48)	5.38 (0.69)		65 8.3 (6.34)	8.48 (0.71)	3.10 (1.14, 5.05) [0.44 (0.10, 0.79)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0561
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.471.4.1: Total, Gender, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 16		121	49.5 (10.08)				117	50.1 (9.57)			
Week 16 chg		119	4.4 (8.65)	4.12	(0.70)		113	3.4 (8.59)	3.70	(0.72)	-0.42 (-2.41, 1.56) 0.675 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1148
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.471.4.1: Total, Gender, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 41.5 (12.42)		57	55 45.5 (9.37)		
Week 16		45 48.2 (11.07)			45 47.8 (11.40)		
Week 16 chg		44 6.2 (9.25)	5.70 (1.34)		43 2.0 (9.99)	2.75 (1.36)	-2.95 (-6.77, 0.88) 0.129 [-0.31 (-0.73, 0.12)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1148
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.471.4.1: Total, Gender, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Male											
Baseline	83	81	47.1 (10.20)			81	79	46.8 (10.02)			
Week 16		76	50.2 (9.43)				72	51.5 (7.99)			
Week 16 chg		75	3.3 (8.14)	3.27	(0.77)		70	4.3 (7.56)	4.30	(0.80)	1.03 (-1.17, 3.23) 0.357 [0.13 (-0.20, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1148
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.472.4.1: Total, Gender, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary									
Total									
Baseline	137	134	44.5 (8.19)		138	134	44.5 (7.83)		
Week 16		121	51.0 (7.75)			117	52.8 (6.79)		
Week 16 chg		119	6.8 (8.15)	6.60 (0.60)		113	8.0 (7.67)	8.20 (0.61)	1.60 (-0.09, 3.28) 0.063 [0.20 (-0.06, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1069
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.472.4.1: Total, Gender, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Female							
Baseline	54	53 44.5 (8.34)		57	55 44.2 (8.08)		
Week 16		45 52.6 (7.58)			45 52.2 (8.33)		
Week 16 chg		44 8.5 (10.08)	8.46 (1.18)		43 8.2 (9.54)	8.28 (1.19)	-0.19 (-3.53, 3.15) 0.912 [-0.02 (-0.44, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1069
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.472.4.1: Total, Gender, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Male								
Baseline	83	81 44.5 (8.15)		81	79 44.8 (7.70)			
Week 16		76 50.0 (7.74)			72 53.1 (5.66)			
Week 16 chg		75 5.8 (6.66)	5.58 (0.63)		70 7.8 (6.33)	8.08 (0.65)	2.50 (0.71, 4.28) [0.38 (0.06, 0.71)]	0.007

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1069
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.4.701.3.1: Total, Any TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Female						43	12.9		127	37.8	
Male						83	25.1		125	37.3	
Any system organ class											
Any preferred term											
Total	0.4074	0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504
Female		0.9683	1.00 (0.79, 1.25)	0.98 (0.45, 2.15)	-0.3 (-16, 15.4)	29	(67.4)	58	91	(71.7)	277
Male		0.2342	1.11 (0.93, 1.33)	1.48 (0.78, 2.82)	7.3 (-4.8, 19.4)	55	(66.3)	126	89	(71.2)	227

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 1.4.701.4.1: Total, Any TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.1951	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385
Female		0.4036	1.09 (0.89, 1.33)	1.46 (0.60, 3.57)	6.7 (-8.9, 22.3)	40	(74.1)	155	46	(80.7)	167
Male		0.3165	0.92 (0.79, 1.08)	0.69 (0.33, 1.44)	-6.4 (-19, 6.25)	68	(81.9)	268	61	(75.3)	218

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 1.4.702.3.1: Total, Any drug-related TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Female						43	12.9		127	37.8	
Male						83	25.1		125	37.3	
Any system organ class											
Any preferred term											
Total	0.3616	0.0023	1.58 (1.16, 2.16)	2.11 (1.30, 3.42)	15.7 (6.11, 25.2)	34	(27.0)	61	108	(42.9)	232
Female		0.3059	1.26 (0.81, 1.96)	1.50 (0.70, 3.20)	8.7 (-7.4, 24.9)	14	(32.6)	24	58	(45.7)	143
Male		0.0080	1.74 (1.13, 2.67)	2.40 (1.25, 4.58)	17.4 (5.28, 29.5)	20	(24.1)	37	50	(40.0)	89

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 1.4.702.4.1: Total, Any drug-related TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.2081	0.2852	1.19 (0.86, 1.65)	1.32 (0.80, 2.17)	6.1 (-5.0, 17.3)	43	(31.4)	94	52	(37.7)	105
Female		0.0915	1.58 (0.92, 2.72)	1.99 (0.89, 4.46)	15.0 (-2.3, 32.2)	14	(25.9)	38	23	(40.4)	48
Male		0.9304	1.02 (0.67, 1.54)	1.03 (0.54, 1.94)	0.7 (-14, 15.4)	29	(34.9)	56	29	(35.8)	57

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 1.4.703.3.1: Total, Any TEAE causing permanent discontinuation, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Female						43 12.9		127 37.8	
Male						83 25.1		125 37.3	
Any system organ class									
Any preferred term									
Total	0.4147	0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1 (0.8)	1	6 (2.4)	8
Female		0.2777			2.6 (-.27, 5.47)	0 (0.0)	0	3 (2.4)	5
Male		0.4658	2.29 (0.23, 22.3)	2.35 (0.23, 24.1)	1.4 (-2.1, 5.00)	1 (1.2)	1	3 (2.4)	3

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 1.4.703.4.1: Total, Any TEAE causing permanent discontinuation, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.0374	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3	(2.2)	4	1	(0.7)	1
Female		0.3173			1.8 (-1.7, 5.26)	0	(0.0)	0	1	(1.8)	1
Male		0.0980	0.00 (not est.)	0.00 (not est.)	-3.5 (-7.4, 0.48)	3	(3.6)	4	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. TEAE: Treatment emergent adverse events

Table 1.4.704.3.1: Total, Any mild TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Female						43	12.9		127	37.8	
Male						83	25.1		125	37.3	
Any system organ class											
Any preferred term											
Total	0.1954	0.1405	1.14 (0.95, 1.36)	1.41 (0.89, 2.23)	7.5 (-2.5, 17.5)	69	(54.8)	132	157	(62.3)	384
Female		0.8434	0.97 (0.74, 1.28)	0.93 (0.44, 1.96)	-1.7 (-18, 14.6)	25	(58.1)	45	79	(62.2)	201
Male		0.0755	1.23 (0.97, 1.55)	1.73 (0.94, 3.17)	11.8 (-1.1, 24.7)	44	(53.0)	87	78	(62.4)	183

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 1.4.704.4.1: Total, Any mild TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.8568	0.9615	1.00 (0.87, 1.16)	1.01 (0.60, 1.71)	0.3 (-10, 10.9)	98	(71.5)	293	99	(71.7)	300
Female		0.8447	1.02 (0.81, 1.30)	1.09 (0.48, 2.46)	1.7 (-15, 18.7)	38	(70.4)	117	41	(71.9)	123
Male		0.9677	1.00 (0.82, 1.20)	0.99 (0.50, 1.94)	-0.3 (-14, 13.6)	60	(72.3)	176	58	(71.6)	177

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 1.4.705.3.1: Total, Any moderate TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Female						43	12.9		127	37.8	
Male						83	25.1		125	37.3	
Any system organ class											
Any preferred term											
Total	0.0413	0.6376	1.09 (0.75, 1.59)	1.13 (0.68, 1.85)	2.2 (-7.0, 11.4)	30	(23.8)	42	66	(26.2)	113
Female		0.0750	1.88 (0.88, 4.03)	2.18 (0.90, 5.29)	14.1 (-.03, 28.2)	7	(16.3)	11	40	(31.5)	72
Male		0.3119	0.78 (0.48, 1.27)	0.71 (0.37, 1.37)	-6.1 (-18, 5.82)	23	(27.7)	31	26	(20.8)	41

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 1.4.705.4.1: Total, Any moderate TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.4942	0.0876	0.75 (0.53, 1.05)	0.65 (0.39, 1.07)	-9.8 (-21, 1.39)	53	(38.7)	121	40	(29.0)	82
Female		0.5238	0.85 (0.52, 1.39)	0.77 (0.35, 1.69)	-5.8 (-24, 11.9)	21	(38.9)	38	19	(33.3)	43
Male		0.0690	0.66 (0.42, 1.04)	0.55 (0.28, 1.06)	-13 (-28, 0.98)	32	(38.6)	83	21	(25.9)	39

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 1.4.706.3.1: Total, Any severe TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Female						43	12.9		127	37.8	
Male						83	25.1		125	37.3	
Any system organ class											
Any preferred term											
Total	0.7865	0.1738	0.50 (0.18, 1.39)	0.48 (0.16, 1.41)	-2.8 (-7.3, 1.68)	7	(5.6)	10	7	(2.8)	7
Female		0.4542	0.49 (0.07, 3.37)	0.48 (0.07, 3.12)	-2.3 (-9.1, 4.48)	2	(4.7)	2	4	(3.1)	4
Male		0.2099	0.41 (0.10, 1.73)	0.40 (0.09, 1.73)	-3.5 (-9.2, 2.30)	5	(6.0)	8	3	(2.4)	3

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 1.4.706.4.1: Total, Any severe TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.0904	0.1235	0.37 (0.10, 1.38)	0.36 (0.09, 1.39)	-3.7 (-8.3, 0.97)	8	(5.8)	9	3	(2.2)	3
Female		0.3458			1.7 (-1.7, 5.06)	0	(0.0)	0	1	(1.8)	1
Male		0.0550	0.25 (0.06, 1.16)	0.24 (0.05, 1.15)	-7.2 (-14, -.01)	8	(9.6)	9	2	(2.5)	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. TEAE: Treatment emergent adverse events

Table 1.4.707.3.1: Total, Death, LP0162-1339, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	ChiSq / p-value	CMH RR / 95%CI	CMH OR / 95%CI	CMH RD / 95%CI	Placebo + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Female					43	12.9		127	37.8	
Male					83	25.1		125	37.3	

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.

Table 1.4.707.4.1: Total, Death, LP0162-1346, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	ChiSq / p-value	CMH RR / 95%CI	CMH OR / 95%CI	CMH RD / 95%CI	Placebo + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Female					54	25.8		57	27.0	
Male					83	39.6		81	38.4	

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.

Table 1.4.708.3.1: Total, Any TE SAE, LP0162-1339, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Analysis set							
N, Exposure(years)							
Total						126 37.9	252 75.0
Female						43 12.9	127 37.8
Male						83 25.1	125 37.3
Any system organ class							
Any preferred term							
Total	0.1902	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4 (3.2) 4	2 (0.8) 2
Female		0.5637			0.8 (-.81, 2.41)	0 (0.0) 0	1 (0.8) 1
Male		0.0744	0.16 (0.02, 1.59)	0.16 (0.02, 1.51)	-3.9 (-8.7, 0.88)	4 (4.8) 4	1 (0.8) 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. TE SAE: Treatment emergent serious adverse events

Table 1.4.708.4.1: Total, Any TE SAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.0213	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5	(3.6)	9	1	(0.7)	1
Female		0.3458			1.7 (-1.7, 5.06)	0	(0.0)	0	1	(1.8)	1
Male		0.0266	0.00 (not est.)	0.00 (not est.)	-6.0 (-11, -.88)	5	(6.0)	9	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 1.4.709.3.1: Total, Any drug-related TE SAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Female					43	12.9		127	37.8	
Male					83	25.1		125	37.3	

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 1.4.709.4.1: Total, Any drug-related TE SAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)		3	0 (0.0)		0
Male		0.1793	0.00 (not est.)	0.00 (not est.)	-2.3 (-5.5, 0.93)	2 (2.4)		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 1.4.710.3.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Female					43	12.9		127	37.8	
Male					83	25.1		125	37.3	

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 1.4.710.4.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Female						54 25.8		57 27.0	
Male						83 39.6		81 38.4	
Any system organ class									
Any preferred term									
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)	3	0 (0.0)	0
Male		0.1793	0.00 (not est.)	0.00 (not est.)	-2.3 (-5.5, 0.93)	2 (2.4)	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 1.4.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Female						43	12.9		127	37.8	
Male						83	25.1		125	37.3	
Any system organ class											
Any preferred term											
Total	0.4074	0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504
Female		0.9683	1.00 (0.79, 1.25)	0.98 (0.45, 2.15)	-0.3 (-16, 15.4)	29	(67.4)	58	91	(71.7)	277
Male		0.2342	1.11 (0.93, 1.33)	1.48 (0.78, 2.82)	7.3 (-4.8, 19.4)	55	(66.3)	126	89	(71.2)	227
Eye disorders											
Any											
Total	0.3258	0.0191	3.12 (1.12, 8.68)	3.50 (1.17, 10.5)	6.7 (2.02, 11.5)	4	(3.2)	5	25	(9.9)	29
Female		0.5500	1.52 (0.38, 6.09)	1.61 (0.33, 7.78)	2.7 (-5.3, 10.6)	2	(4.7)	3	12	(9.4)	14
Male		0.0231	4.76 (1.06, 21.4)	5.40 (1.12, 26.0)	8.4 (2.17, 14.6)	2	(2.4)	2	13	(10.4)	15
Gastrointestinal disorders											
Any											
Total	0.9664	0.2711	1.49 (0.73, 3.06)	1.55 (0.71, 3.40)	3.5 (-2.4, 9.43)	9	(7.1)	10	27	(10.7)	30
General disorders and administration site conditions											
Any											
Total	0.0985	0.0459	1.81 (0.99, 3.31)	1.99 (1.00, 3.94)	7.7 (0.80, 14.6)	12	(9.5)	13	43	(17.1)	66
Female		0.0285	3.92 (0.99, 15.5)	4.65 (1.05, 20.6)	14.2 (4.59, 23.8)	2	(4.7)	2	25	(19.7)	42
Male		0.5590	1.24 (0.60, 2.59)	1.28 (0.56, 2.95)	2.8 (-6.5, 12.2)	10	(12.0)	11	18	(14.4)	24

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 1.4.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Injection site reaction									
Total	1.0000	0.0026			6.7 (3.63, 9.81)	0 (0.0)	0	17 (6.7)	30
Female		0.0336			9.3 (4.09, 14.5)	0 (0.0)	0	10 (7.9)	20
Male		0.0383			5.1 (1.22, 8.99)	0 (0.0)	0	7 (5.6)	10
Infections and infestations									
Any									
Total	0.5191	0.0346	1.30 (1.01, 1.69)	1.63 (1.03, 2.56)	11.1 (0.97, 21.2)	46 (36.5)	72	120 (47.6)	186
Female		0.1158	1.38 (0.89, 2.14)	1.78 (0.86, 3.72)	13.5 (-3.2, 30.2)	15 (34.9)	22	68 (53.5)	106
Male		0.3676	1.16 (0.83, 1.64)	1.31 (0.73, 2.35)	6.0 (-7.2, 19.2)	31 (37.3)	50	52 (41.6)	80
Upper respiratory tract infection									
Total	0.6370	0.3271	1.55 (0.64, 3.79)	1.60 (0.62, 4.11)	2.6 (-2.3, 7.57)	6 (4.8)	7	19 (7.5)	21
Conjunctivitis									
Total	0.1279	0.0087	3.46 (1.25, 9.58)	3.95 (1.33, 11.7)	7.8 (2.97, 12.7)	4 (3.2)	4	28 (11.1)	32
Female		0.7668	1.24 (0.30, 5.13)	1.28 (0.26, 6.36)	1.2 (-6.5, 8.94)	2 (4.7)	2	10 (7.9)	11
Male		0.0026	6.61 (1.50, 29.0)	7.76 (1.70, 35.4)	12.5 (5.57, 19.5)	2 (2.4)	2	18 (14.4)	21
Viral upper respiratory tract infection									
Total	0.7354	0.0363	1.75 (1.02, 3.01)	2.00 (1.04, 3.85)	8.3 (1.16, 15.4)	14 (11.1)	18	49 (19.4)	64
Female		0.1766	1.93 (0.70, 5.35)	2.18 (0.70, 6.81)	8.7 (-2.3, 19.8)	4 (9.3)	5	27 (21.3)	36
Male		0.1939	1.57 (0.79, 3.13)	1.74 (0.76, 4.02)	6.6 (-2.8, 16.0)	10 (12.0)	13	22 (17.6)	28
Injury, poisoning and procedural complications									
Any									
Total	0.1528	0.5974	1.31 (0.48, 3.60)	1.32 (0.46, 3.77)	1.2 (-3.2, 5.63)	5 (4.0)	6	13 (5.2)	14
Musculoskeletal and connective tissue disorders									
Any									

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 1.4.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Total	0.4871	0.2269	1.79 (0.68, 4.68)	1.86 (0.67, 5.14)	3.2 (-1.5, 7.81)	5 (4.0)	6	18 (7.1)	20
Nervous system disorders									
Any									
Total	0.7478	0.1130	1.80 (0.85, 3.78)	1.93 (0.85, 4.40)	5.1 (-.65, 10.8)	8 (6.3)	11	29 (11.5)	37
Headache									
Total	0.4304	0.1663	1.81 (0.77, 4.29)	1.93 (0.75, 4.95)	3.9 (-1.1, 8.91)	6 (4.8)	9	22 (8.7)	26
Respiratory, thoracic and mediastinal disorders									
Any									
Total	0.7488	0.5541	1.21 (0.64, 2.28)	1.24 (0.61, 2.50)	2.0 (-4.5, 8.52)	12 (9.5)	14	29 (11.5)	39
Skin and subcutaneous tissue disorders									
Any									
Total	0.8311	0.0628	0.63 (0.38, 1.02)	0.58 (0.32, 1.03)	-7.1 (-15, 0.81)	24 (19.0)	28	30 (11.9)	36
Dermatitis atopic									
Total	0.4327	0.0125	0.30 (0.11, 0.82)	0.28 (0.10, 0.80)	-5.5 (-11, -.44)	10 (7.9)	12	6 (2.4)	8
Female		0.0859	0.10 (0.00, 2.48)	0.10 (0.01, 1.72)	-4.0 (-10, 2.33)	2 (4.7)	2	1 (0.8)	1
Male		0.1277	0.43 (0.14, 1.32)	0.41 (0.13, 1.30)	-5.3 (-12, 1.85)	8 (9.6)	10	5 (4.0)	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 1.4.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.1951	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385
Female		0.4036	1.09 (0.89, 1.33)	1.46 (0.60, 3.57)	6.7 (-8.9, 22.3)	40	(74.1)	155	46	(80.7)	167
Male		0.3165	0.92 (0.79, 1.08)	0.69 (0.33, 1.44)	-6.4 (-19, 6.25)	68	(81.9)	268	61	(75.3)	218
Eye disorders											
Any											
Total	0.7079	0.2842	1.54 (0.69, 3.44)	1.61 (0.67, 3.84)	3.6 (-3.0, 10.1)	9	(6.6)	14	14	(10.1)	17
Gastrointestinal disorders											
Any											
Total	0.2731	0.8349	0.93 (0.48, 1.81)	0.92 (0.44, 1.95)	-0.8 (-8.3, 6.68)	16	(11.7)	23	15	(10.9)	18
General disorders and administration site conditions											
Any											
Total	0.0366	0.1576	1.59 (0.83, 3.03)	1.70 (0.81, 3.57)	5.6 (-2.1, 13.3)	13	(9.5)	16	21	(15.2)	27
Infections and infestations											
Any											
Total	0.3253	0.2533	0.89 (0.72, 1.09)	0.76 (0.47, 1.22)	-6.8 (-18, 4.82)	83	(60.6)	152	74	(53.6)	144

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 1.4.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Upper respiratory tract infection											
Total	0.9154	0.9930	1.00 (0.43, 2.31)	1.00 (0.40, 2.47)	-0.0 (-6.2, 6.12)	10	(7.3)	11	10	(7.2)	12
Viral upper respiratory tract infection											
Total	0.3051	0.7928	1.05 (0.71, 1.57)	1.08 (0.63, 1.84)	1.4 (-9.0, 11.8)	35	(25.5)	46	37	(26.8)	53
Injury, poisoning and procedural complications											
Any											
Total	0.9487	0.5243	1.29 (0.59, 2.84)	1.32 (0.56, 3.08)	2.1 (-4.5, 8.74)	10	(7.3)	12	13	(9.4)	16
Musculoskeletal and connective tissue disorders											
Any											
Total	0.4259	0.4116	1.27 (0.72, 2.24)	1.32 (0.68, 2.57)	3.5 (-4.9, 12.0)	18	(13.1)	28	23	(16.7)	25
Nervous system disorders											
Any											
Total	0.1530	0.6516	1.13 (0.66, 1.94)	1.16 (0.61, 2.20)	2.0 (-6.7, 10.8)	21	(15.3)	31	24	(17.4)	33
Headache											
Total	0.5520	0.1506	1.61 (0.84, 3.09)	1.71 (0.82, 3.57)	5.7 (-2.0, 13.5)	13	(9.5)	18	21	(15.2)	25
Respiratory, thoracic and mediastinal disorders											
Any											
Total	0.6610	0.0335	0.55 (0.31, 0.96)	0.49 (0.25, 0.95)	-9.5 (-18, -.84)	29	(21.2)	38	16	(11.6)	21
Female		0.0913	0.47 (0.19, 1.17)	0.42 (0.15, 1.18)	-12 (-26, 1.97)	12	(22.2)	13	6	(10.5)	7
Male		0.1662	0.61 (0.30, 1.24)	0.56 (0.24, 1.29)	-8.1 (-19, 3.32)	17	(20.5)	25	10	(12.3)	14
Skin and subcutaneous tissue disorders											
Any											

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 1.4.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Total	0.4765	0.1365	0.71 (0.46, 1.12)	0.65 (0.37, 1.15)	-7.5 (-17, 2.33)	36 (26.3) 59	26 (18.8) 44
Dermatitis atopic							
Total	0.8395	0.0498	0.44 (0.19, 1.03)	0.41 (0.16, 1.02)	-6.6 (-13, -.07)	16 (11.7) 26	7 (5.1) 11
Female		0.2095	0.38 (0.08, 1.84)	0.35 (0.07, 1.89)	-5.8 (-15, 3.27)	5 (9.3) 6	2 (3.5) 2
Male		0.1316	0.47 (0.17, 1.29)	0.43 (0.14, 1.31)	-7.0 (-16, 1.97)	11 (13.3) 20	5 (6.2) 9
Vascular disorders							
Any							
Total	0.7650	0.0596	0.36 (0.12, 1.10)	0.34 (0.10, 1.09)	-5.2 (-11, 0.16)	11 (8.0) 12	4 (2.9) 6

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 1.4.712.3.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Female						43 12.9		127 37.8	
Male						83 25.1		125 37.3	
Any system organ class									
Any preferred term									
Total	0.1902	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4 (3.2)	4	2 (0.8)	2
Female		0.5637			0.8 (-.81, 2.41)	0 (0.0)	0	1 (0.8)	1
Male		0.0744	0.16 (0.02, 1.59)	0.16 (0.02, 1.51)	-3.9 (-8.7, 0.88)	4 (4.8)	4	1 (0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.4.712.4.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.0213	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5	(3.6)	9	1	(0.7)	1
Female		0.3458			1.7 (-1.7, 5.06)	0	(0.0)	0	1	(1.8)	1
Male		0.0266	0.00 (not est.)	0.00 (not est.)	-6.0 (-11, -.88)	5	(6.0)	9	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 1.4.713.3.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Female						43	12.9		127	37.8	
Male						83	25.1		125	37.3	
Any system organ class											
Any preferred term											
Total	0.4147	0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1	(0.8)	1	6	(2.4)	8
Female		0.2777			2.6 (-.27, 5.47)	0	(0.0)	0	3	(2.4)	5
Male		0.4658	2.29 (0.23, 22.3)	2.35 (0.23, 24.1)	1.4 (-2.1, 5.00)	1	(1.2)	1	3	(2.4)	3
General disorders and administration site conditions											
Any											
Total	1.0000	0.3123			0.8 (-.30, 1.91)	0	(0.0)	0	2	(0.8)	2
Injection site reaction											
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0	(0.0)	0	1	(0.4)	1
Hernia											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	1
Infections and infestations											
Any											
Total	1.0000	0.2229			1.2 (-.15, 2.52)	0	(0.0)	0	3	(1.2)	3
Influenza											
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0	(0.0)	0	1	(0.4)	1
Conjunctivitis											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	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. TE SAE: Treatment emergent serious adverse events

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Table 1.4.713.3.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Otitis media									
Total	Not est.	0.4954			0.4 (-.38, 1.14)	0 (0.0)	0	1 (0.4)	1
Musculoskeletal and connective tissue disorders									
Any									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Myalgia									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Psychiatric disorders									
Any									
Total	Not est.	0.3123			0.8 (-.30, 1.91)	0 (0.0)	0	2 (0.8)	2
Mood altered									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Anxiety									
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0 (0.0)	0	1 (0.4)	1
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Dermatitis atopic									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.4.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.0374	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3	(2.2)	4	1	(0.7)	1
Female		0.3173			1.8 (-1.7, 5.26)	0	(0.0)	0	1	(1.8)	1
Male		0.0980	0.00 (not est.)	0.00 (not est.)	-3.5 (-7.4, 0.48)	3	(3.6)	4	0	(0.0)	0
General disorders and administration site conditions											
Any											
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0	(0.0)	0	1	(0.7)	1
Injection site pain											
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0	(0.0)	0	1	(0.7)	1
Nervous system disorders											
Any											
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1	(0.7)	1	0	(0.0)	0
Cerebrovascular accident											
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1	(0.7)	1	0	(0.0)	0
Psychiatric disorders											
Any											
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1	(0.7)	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

Table 1.4.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Depressed mood									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Suicidal ideation									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis atopic									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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. TE SAE: Treatment emergent serious adverse events

Table 1.4.714.3.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Female						43	12.9		127	37.8	
Male						83	25.1		125	37.3	
Any system organ class											
Any preferred term											
Total	0.0016	0.0185	2.40 (1.10, 5.22)	2.71 (1.15, 6.37)	7.8 (2.10, 13.5)	7	(5.6)	7	34	(13.5)	39
Female		0.3356	0.62 (0.24, 1.61)	0.56 (0.17, 1.82)	-4.7 (-15, 5.83)	5	(11.6)	5	12	(9.4)	14
Male		0.0004	8.15 (1.90, 35.0)	10.5 (2.29, 47.7)	16.0 (8.58, 23.4)	2	(2.4)	2	22	(17.6)	25
Eye disorders											
Any											
Total	0.0110	0.6213	1.48 (0.31, 7.12)	1.50 (0.30, 7.61)	0.8 (-2.1, 3.64)	2	(1.6)	2	6	(2.4)	7
Keratitis											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	1
Conjunctivitis allergic											
Total	0.0209	0.8018	1.23 (0.25, 6.16)	1.24 (0.23, 6.53)	0.4 (-2.4, 3.13)	2	(1.6)	2	5	(2.0)	6
Infections and infestations											
Any											
Total	0.0374	0.0205	2.77 (1.10, 7.00)	3.04 (1.14, 8.11)	7.0 (1.91, 12.1)	5	(4.0)	5	28	(11.1)	32
Female		0.8405	0.88 (0.25, 3.12)	0.86 (0.21, 3.49)	-0.9 (-9.7, 7.91)	3	(7.0)	3	10	(7.9)	11
Male		0.0026	6.61 (1.50, 29.0)	7.76 (1.70, 35.4)	12.5 (5.57, 19.5)	2	(2.4)	2	18	(14.4)	21
Conjunctivitis viral											
Total	Not est.	0.1605	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1	(0.8)	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 1.4.714.3.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	 (%)	 E	Tralokinumab Q2W + TCS n	 (%)	 E
Conjunctivitis											
Total	0.1279	0.0087	3.46 (1.25, 9.58)	3.95 (1.33, 11.7)	7.8 (2.97, 12.7)	4	(3.2)	4	28	(11.1)	32
Female		0.7668	1.24 (0.30, 5.13)	1.28 (0.26, 6.36)	1.2 (-6.5, 8.94)	2	(4.7)	2	10	(7.9)	11
Male		0.0026	6.61 (1.50, 29.0)	7.76 (1.70, 35.4)	12.5 (5.57, 19.5)	2	(2.4)	2	18	(14.4)	21

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 1.4.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	Test for interaction	CMH p-value	CMH RR 95%CI	CMH OR 95%CI	CMH RD 95%CI	Placebo + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.6663	0.0780	2.14 (0.90, 5.07)	2.28 (0.90, 5.77)	5.8 (-.58, 12.2)	7	(5.1)	9	15	(10.9)	17
Female		0.1755	2.75 (0.60, 12.7)	2.97 (0.57, 15.4)	6.7 (-2.8, 16.1)	2	(3.7)	3	6	(10.5)	7
Male		0.2507	1.83 (0.64, 5.17)	1.93 (0.62, 5.99)	5.0 (-3.6, 13.6)	5	(6.0)	6	9	(11.1)	10
Eye disorders											
Any											
Total	0.1192	0.1593	2.23 (0.71, 7.03)	2.30 (0.70, 7.57)	3.6 (-1.4, 8.64)	4	(2.9)	4	9	(6.5)	11
Lacrimation increased											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Exposure keratitis											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Atopic keratoconjunctivitis											
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0	(0.0)	0	1	(0.7)	1
Conjunctivitis allergic											
Total	0.1318	0.5286	1.48 (0.43, 5.11)	1.50 (0.42, 5.40)	1.4 (-3.0, 5.88)	4	(2.9)	4	6	(4.3)	8
Infections and infestations											
Any											
Total	0.9530	0.5286	1.49 (0.43, 5.24)	1.51 (0.42, 5.49)	1.4 (-3.0, 5.84)	4	(2.9)	5	6	(4.3)	6

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 1.4.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Herpes ophthalmic									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Keratitis viral									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Conjunctivitis									
Total	0.9854	0.1591	2.96 (0.61, 14.5)	3.05 (0.60, 15.4)	2.9 (-1.1, 6.81)	2 (1.5)	3	6 (4.3)	6

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 1.4.715.3.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Female					43	12.9		127	37.8	
Male					83	25.1		125	37.3	

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 1.4.715.4.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Female					54	25.8		57	27.0	
Male					83	39.6		81	38.4	

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 1.4.716.3.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Female						43 12.9		127 37.8	
Male						83 25.1		125 37.3	
Any system organ class									
Any preferred term									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	1
Female		0.2801	0.20 (0.01, 5.33)	0.20 (0.01, 4.15)	-1.9 (-6.7, 2.83)	1 (2.3)	1	1 (0.8)	1
Infections and infestations									
Any									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	1
Eczema herpeticum									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	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 1.4.716.4.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	2
Male		0.2895			1.3 (-1.2, 3.75)	0	(0.0)	0	1	(1.2)	2
Infections and infestations											
Any											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	2
Eczema herpeticum											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	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 1.4.717.3.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Female					43	12.9		127	37.8	
Male					83	25.1		125	37.3	

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 1.4.717.4.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Female					54	25.8		57	27.0	
Male					83	39.6		81	38.4	

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 1.4.718.3.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Female					43	12.9		127	37.8	
Male					83	25.1		125	37.3	

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 1.4.718.4.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Female					54	25.8		57	27.0	
Male					83	39.6		81	38.4	

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 1.4.719.3.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Female					43	12.9		127	37.8	
Male					83	25.1		125	37.3	

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 1.4.719.4.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Female					54	25.8		57	27.0	
Male					83	39.6		81	38.4	

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 1.4.720.3.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Analysis set							
N, Exposure(years)							
Total						126 37.9	252 75.0
Female						43 12.9	127 37.8
Male						83 25.1	125 37.3
Any system organ class							
Any preferred term							
Total	0.8999	0.0327	0.29 (0.09, 0.97)	0.27 (0.08, 0.96)	-3.9 (-8.2, 0.34)	7 (5.6) 9	4 (1.6) 4
Female		0.5267	0.39 (0.02, 8.08)	0.39 (0.02, 7.21)	-1.3 (-6.0, 3.35)	1 (2.3) 1	1 (0.8) 1
Male		0.0897	0.32 (0.08, 1.29)	0.31 (0.08, 1.27)	-4.9 (-11, 1.31)	6 (7.2) 8	3 (2.4) 3
Infections and infestations							
Any							
Total	0.8999	0.0327	0.29 (0.09, 0.97)	0.27 (0.08, 0.96)	-3.9 (-8.2, 0.34)	7 (5.6) 9	4 (1.6) 4
Female		0.5267	0.39 (0.02, 8.08)	0.39 (0.02, 7.21)	-1.3 (-6.0, 3.35)	1 (2.3) 1	1 (0.8) 1
Male		0.0897	0.32 (0.08, 1.29)	0.31 (0.08, 1.27)	-4.9 (-11, 1.31)	6 (7.2) 8	3 (2.4) 3
Infected dermal cyst							
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0) 0	1 (0.4) 1
Paronychia							
Total	Not est.	0.1675	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8) 1	0 (0.0) 0
Cellulitis							
Total	0.3693	0.9983	1.00 (0.09, 11.2)	1.00 (0.09, 11.1)	-0.0 (-1.9, 1.90)	1 (0.8) 1	2 (0.8) 2
Impetigo							
Total	Not est.	0.6369	0.52 (0.03, 8.40)	0.52 (0.03, 8.30)	-0.4 (-2.1, 1.35)	1 (0.8) 1	1 (0.4) 1
Dermatitis infected							
Total	1.0000	0.0048	0.00 (not est.)	0.00 (not est.)	-3.2 (-6.2, -.11)	4 (3.2) 6	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

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Table 1.4.720.3.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Female		0.1573	0.00 (not est.)	0.00 (not est.)	-2.1 (-6.5, 2.21)	1 (2.3)	1	0 (0.0)	0
Male		0.0378	0.00 (not est.)	0.00 (not est.)	-3.6 (-7.6, 0.43)	3 (3.6)	5	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 1.4.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Female						54 25.8		57 27.0	
Male						83 39.6		81 38.4	
Any system organ class									
Any preferred term									
Total	0.4531	0.0178	0.12 (0.02, 0.99)	0.12 (0.01, 0.96)	-5.1 (-9.3, -.93)	8 (5.8)	12	1 (0.7)	1
Female		0.1451	0.00 (not est.)	0.00 (not est.)	-3.7 (-8.8, 1.33)	2 (3.7)	3	0 (0.0)	0
Male		0.0602	0.16 (0.02, 1.44)	0.16 (0.02, 1.37)	-6.0 (-12, 0.07)	6 (7.2)	9	1 (1.2)	1
Infections and infestations									
Any									
Total	0.4210	0.0311	0.14 (0.02, 1.15)	0.13 (0.02, 1.12)	-4.4 (-8.3, -.44)	7 (5.1)	11	1 (0.7)	1
Female		0.1451	0.00 (not est.)	0.00 (not est.)	-3.7 (-8.8, 1.33)	2 (3.7)	3	0 (0.0)	0
Male		0.1025	0.20 (0.02, 1.75)	0.19 (0.02, 1.69)	-4.8 (-10, 0.81)	5 (6.0)	8	1 (1.2)	1
Staphylococcal skin infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Wound infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Cellulitis									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Oral herpes									
Total	Not est.	0.3067	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.2, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis infected									
Total	Not est.	0.1718	0.24 (0.03, 2.19)	0.24 (0.03, 2.19)	-2.2 (-5.4, 0.94)	4 (2.9)	7	1 (0.7)	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

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Table 1.4.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Hand dermatitis									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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 1.4.721.3.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Female						43 12.9		127 37.8	
Male						83 25.1		125 37.3	
Any system organ class									
Any preferred term									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Male		0.2650	0.00 (not est.)	0.00 (not est.)	-1.1 (-3.4, 1.15)	1 (1.2)	1	0 (0.0)	0
Infections and infestations									
Any									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Dermatitis infected									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	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. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.4.721.4.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Female					54	25.8		57	27.0	
Male					83	39.6		81	38.4	

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 1.4.722.3.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Female						43	12.9		127	37.8	
Male						83	25.1		125	37.3	
Any system organ class											
Any preferred term											
Total	0.5181	0.1972	1.10 (0.95, 1.27)	1.37 (0.85, 2.22)	6.2 (-3.3, 15.8)	81	(64.3)	168	178	(70.6)	494
Female		0.8011	1.03 (0.81, 1.31)	1.10 (0.51, 2.37)	2.0 (-14, 18.1)	28	(65.1)	54	91	(71.7)	274
Male		0.2003	1.13 (0.93, 1.37)	1.51 (0.80, 2.85)	8.0 (-4.3, 20.4)	53	(63.9)	114	87	(69.6)	220

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 1.4.722.4.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Female						54	25.8		57	27.0	
Male						83	39.6		81	38.4	
Any system organ class											
Any preferred term											
Total	0.3208	0.8030	0.98 (0.87, 1.12)	0.93 (0.53, 1.64)	-1.3 (-11, 8.62)	107	(78.1)	391	106	(76.8)	361
Female		0.5385	1.07 (0.87, 1.31)	1.32 (0.55, 3.16)	5.0 (-11, 20.9)	40	(74.1)	149	45	(78.9)	160
Male		0.4255	0.94 (0.80, 1.10)	0.74 (0.36, 1.55)	-5.2 (-18, 7.61)	67	(80.7)	242	61	(75.3)	201

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 1.4.723.3.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Analysis set							
N, Exposure(years)							
Total						126 37.9	252 75.0
Female						43 12.9	127 37.8
Male						83 25.1	125 37.3
Any system organ class							
Any preferred term							
Total	0.1902	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4 (3.2) 4	2 (0.8) 2
Female		0.5637			0.8 (-.81, 2.41)	0 (0.0) 0	1 (0.8) 1
Male		0.0744	0.16 (0.02, 1.59)	0.16 (0.02, 1.51)	-3.9 (-8.7, 0.88)	4 (4.8) 4	1 (0.8) 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. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.4.723.4.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Female						54 25.8		57 27.0	
Male						83 39.6		81 38.4	
Any system organ class									
Any preferred term									
Total	0.0213	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5 (3.6)	8	1 (0.7)	1
Female		0.3458			1.7 (-1.7, 5.06)	0 (0.0)	0	1 (1.8)	1
Male		0.0266	0.00 (not est.)	0.00 (not est.)	-6.0 (-11, -.88)	5 (6.0)	8	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.

Table 1.6.101.3.1.1: Total, Europe, Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	72	147
Age (years)		
Mean (sd)	36.5 (13.7)	38.0 (13.3)
Gender		
Female	18 (25.0%)	71 (48.3%)
Male	54 (75.0%)	76 (51.7%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	25.3 (3.7)	26.1 (5.9)
Race		
Asian	6 (8.3%)	4 (2.7%)
Black	2 (2.8%)	4 (2.7%)
White	62 (86.1%)	137 (93.2%)
Other	2 (2.8%)	2 (1.4%)
Geographic region		
Europe	72 (100%)	147 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	54.6 (26.2)	52.3 (24.0)
Duration of AD (years)		
Mean (sd)	29.5 (14.7)	28.7 (15.1)
Eczema Area and Severity Index (EASI)		
Mean (sd)	32.0 (13.6)	30.7 (12.1)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	33 (45.8%)	71 (48.3%)
Severe [IGA=4]	39 (54.2%)	76 (51.7%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.6 (1.4)	7.6 (1.5)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.7 (2.1)	6.8 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	69.8 (13.2)	68.2 (13.1)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	16.6 (7.2)	18.3 (6.9)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	12.5 (7.5)	12.3 (7.5)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	52.8 (21.6)	50.0 (23.9)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.570 (0.28)	0.537 (0.26)
Patients that have tried systemic corticosteroids (%)		
No	19 (26.4%)	59 (40.1%)
Yes	53 (73.6%)	88 (59.9%)
Previous number of treatments with systemic immunosuppressants*		
0	28 (38.9%)	72 (49.0%)
1	25 (34.7%)	52 (35.4%)
2	14 (19.4%)	15 (10.2%)
3	3 (4.2%)	4 (2.7%)
4	1 (1.4%)	4 (2.7%)
5	1 (1.4%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.6.101.3.2.1: Total, Rest of World, Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	54	105
Age (years)		
Mean (sd)	39.4 (16.2)	42.2 (17.6)
Gender		
Female	25 (46.3%)	56 (53.3%)
Male	29 (53.7%)	49 (46.7%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	29.3 (6.7)	29.6 (7.2)
Race		
Asian	18 (33.3%)	13 (12.4%)
Black	10 (18.5%)	18 (17.1%)
White	22 (40.7%)	66 (62.9%)
Other	4 (7.4%)	8 (7.6%)
Geographic region		
USA	54 (100%)	105 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	41.2 (23.6)	40.9 (20.6)
Duration of AD (years)		
Mean (sd)	27.7 (15.7)	26.8 (18.1)
Eczema Area and Severity Index (EASI)		
Mean (sd)	28.3 (11.4)	26.2 (11.4)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	33 (61.1%)	65 (61.9%)
Severe [IGA=4]	21 (38.9%)	40 (38.1%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	8.2 (1.6)	7.7 (1.6)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.6 (2.2)	7.0 (2.2)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	67.5 (13.2)	65.2 (13.4)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	18.0 (7.1)	16.5 (7.3)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	10.9 (7.8)	10.8 (7.1)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	68.4 (22.2)	71.9 (20.6)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.614 (0.28)	0.596 (0.30)
Patients that have tried systemic corticosteroids (%)		
No	22 (40.7%)	46 (43.8%)
Yes	32 (59.3%)	59 (56.2%)
Previous number of treatments with systemic immunosuppressants*		
0	34 (63.0%)	87 (82.9%)
1	14 (25.9%)	12 (11.4%)
2	4 (7.4%)	4 (3.8%)
3	2 (3.7%)	1 (1.0%)
5		1 (1.0%)

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.6.102.3.1: Total, Europe, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Europe				
Analysis set				
N	72		147	
Blood and lymphatic system disorders				
Lymphadenopathy	1	(1.4)		
Dermatopathic lymphadenopathy			1	(0.7)
Eosinophilia			1	(0.7)
Hypercoagulation			1	(0.7)
Hypereosinophilic syndrome			1	(0.7)
Iron deficiency anaemia			1	(0.7)
Leukocytosis			1	(0.7)
Lymphadenitis			1	(0.7)
Cardiac disorders				
Arrhythmia			1	(0.7)
Bradycardia			1	(0.7)
Congenital, familial and genetic disorders				
Atrial septal defect	2	(2.8)		
Ichthyosis	2	(2.8)	1	(0.7)
Gilbert's syndrome	1	(1.4)		
Thalassaemia beta	1	(1.4)		
Type V hyperlipidaemia			1	(0.7)
Ear and labyrinth disorders				
Hyperacusis	1	(1.4)		
Vertigo			2	(1.4)
Deafness bilateral			1	(0.7)
Endocrine disorders				
Hypothyroidism	1	(1.4)	6	(4.1)
Autoimmune thyroiditis			2	(1.4)
Basedow's disease			1	(0.7)
Thyroid mass			1	(0.7)
Eye disorders				
Conjunctivitis allergic	14	(19.4)	39	(26.5)
Atopic keratoconjunctivitis	4	(5.6)	5	(3.4)
Dry eye			3	(2.0)
Blepharitis	1	(1.4)	1	(0.7)
Blindness unilateral	1	(1.4)		
Cataract	1	(1.4)	2	(1.4)
Keratitis	1	(1.4)		
Keratoconus	1	(1.4)		
Glaucoma			2	(1.4)
Allergic keratitis			1	(0.7)
Astigmatism			1	(0.7)
Blindness			1	(0.7)
Blindness day			1	(0.7)
Corneal opacity			1	(0.7)
Eczema eyelids			1	(0.7)
Eyelid oedema			1	(0.7)
Myopia			1	(0.7)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	1	(1.4)	5	(3.4)
Cheilitis	1	(1.4)		
Chronic gastritis	1	(1.4)		
Constipation	1	(1.4)		
Diarrhoea	1	(1.4)		
Hiatus hernia	1	(1.4)		
Abdominal distension			1	(0.7)
Crohn's disease			1	(0.7)
Haemorrhoids			1	(0.7)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.6.102.3.1: Total, Europe, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Europe				
Gastrointestinal disorders				
Irritable bowel syndrome			1	(0.7)
Oesophagitis			1	(0.7)
General disorders and administration site conditions				
Fatigue	1	(1.4)		
Drug intolerance			2	(1.4)
Drug chemical incompatibility			1	(0.7)
Gait disturbance			1	(0.7)
Hernia			1	(0.7)
Hepatobiliary disorders				
Hyperbilirubinaemia	1	(1.4)		
Immune system disorders				
Seasonal allergy	34	(47.2)	74	(50.3)
Food allergy	24	(33.3)	45	(30.6)
Mite allergy	4	(5.6)	5	(3.4)
Multiple allergies	2	(2.8)	7	(4.8)
Allergy to animal	3	(4.2)	6	(4.1)
Drug hypersensitivity	3	(4.2)	4	(2.7)
Rubber sensitivity	3	(4.2)	3	(2.0)
Sensitisation	2	(2.8)		
Hypersensitivity	1	(1.4)	3	(2.0)
Allergy to chemicals	1	(1.4)		
Allergy to metals			2	(1.4)
Allergy to arthropod sting			1	(0.7)
Milk allergy			1	(0.7)
Mycotic allergy			1	(0.7)
Reaction to colouring			1	(0.7)
Infections and infestations				
Herpes simplex	4	(5.6)	4	(2.7)
Rhinitis	2	(2.8)	2	(1.4)
Oral herpes			4	(2.7)
Eczema herpeticum	1	(1.4)	1	(0.7)
Conjunctivitis			1	(0.7)
Conjunctivitis bacterial			1	(0.7)
Onychomycosis			1	(0.7)
Viral upper respiratory tract infection			1	(0.7)
Injury, poisoning and procedural complications				
Ligament rupture	1	(1.4)		
Muscle strain	1	(1.4)		
Joint injury			1	(0.7)
Investigations				
Alanine aminotransferase increased	1	(1.4)	1	(0.7)
Basophil count decreased	1	(1.4)		
Blood bilirubin increased	1	(1.4)		
Blood immunoglobulin E increased	1	(1.4)	2	(1.4)
Blood lactate dehydrogenase increased	1	(1.4)		
Blood triglycerides increased	1	(1.4)		
Electrocardiogram QT shortened	1	(1.4)		
Gamma-glutamyltransferase increased	1	(1.4)	1	(0.7)
Low density lipoprotein increased	1	(1.4)	1	(0.7)
Mean cell volume decreased	1	(1.4)		
Blood cholesterol increased			2	(1.4)
Hepatic enzyme increased			1	(0.7)
Human papilloma virus test			1	(0.7)
Metabolism and nutrition disorders				
Obesity	1	(1.4)	7	(4.8)
Diabetes mellitus	1	(1.4)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.6.102.3.1: Total, Europe, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Europe				
Metabolism and nutrition disorders				
Dyslipidaemia	1	(1.4)		
Haemochromatosis	1	(1.4)		
Lactose intolerance	1	(1.4)	2	(1.4)
Vitamin D deficiency	1	(1.4)	2	(1.4)
Hypercholesterolaemia			2	(1.4)
Hyperlipidaemia			2	(1.4)
Decreased appetite			1	(0.7)
Fructose intolerance			1	(0.7)
Glucose tolerance impaired			1	(0.7)
Gout			1	(0.7)
Hypertriglyceridaemia			1	(0.7)
Hyperuricaemia			1	(0.7)
Iodine deficiency			1	(0.7)
Type 2 diabetes mellitus			1	(0.7)
Vitamin B12 deficiency			1	(0.7)
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion			3	(2.0)
Osteoarthritis			3	(2.0)
Ankylosing spondylitis	1	(1.4)	1	(0.7)
Arthritis	1	(1.4)	1	(0.7)
Joint instability	1	(1.4)		
Systemic lupus erythematosus	1	(1.4)		
Arthralgia			1	(0.7)
Back pain			1	(0.7)
Costochondritis			1	(0.7)
Haemarthrosis			1	(0.7)
Intervertebral disc disorder			1	(0.7)
Limb asymmetry			1	(0.7)
Muscle spasms			1	(0.7)
Muscle tightness			1	(0.7)
Muscular weakness			1	(0.7)
Osteonecrosis			1	(0.7)
Osteoporosis			1	(0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Haemangioma	1	(1.4)		
Skin papilloma	1	(1.4)		
Leiomyoma			1	(0.7)
Lipoma			1	(0.7)
Uterine leiomyoma			1	(0.7)
Nervous system disorders				
Headache	2	(2.8)	3	(2.0)
Seizure	1	(1.4)		
Tension headache	1	(1.4)		
Migraine			2	(1.4)
Epilepsy			1	(0.7)
Lumbar radiculopathy			1	(0.7)
Psychiatric disorders				
Depression			7	(4.8)
Autism spectrum disorder	3	(4.2)		
Anxiety	1	(1.4)	2	(1.4)
Anxiety disorder	1	(1.4)		
Attention deficit/hyperactivity disorder	1	(1.4)		
Depersonalisation/derealisation disorder	1	(1.4)		
Stress	1	(1.4)		
Bulimia nervosa			1	(0.7)
Sleep disorder			1	(0.7)
Renal and urinary disorders				
Renal colic	1	(1.4)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.6.102.3.1: Total, Europe, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Europe				
Renal and urinary disorders				
Renal cyst	1	(1.4)		
Chronic kidney disease			1	(0.7)
Renal failure			1	(0.7)
Reproductive system and breast disorders				
Benign prostatic hyperplasia			1	(0.7)
Dysmenorrhoea			1	(0.7)
Respiratory, thoracic and mediastinal disorders				
Asthma	34	(47.2)	66	(44.9)
Rhinitis allergic	9	(12.5)	11	(7.5)
Sleep apnoea syndrome			3	(2.0)
Chronic obstructive pulmonary disease	1	(1.4)	2	(1.4)
Nasal polyps	1	(1.4)		
Rhinitis perennial	1	(1.4)		
Skin and subcutaneous tissue disorders				
Androgenetic alopecia	3	(4.2)	3	(2.0)
Alopecia	2	(2.8)	1	(0.7)
Alopecia areata	2	(2.8)	2	(1.4)
Dermatitis contact	1	(1.4)	3	(2.0)
Alopecia universalis	1	(1.4)		
Dermal cyst	1	(1.4)		
Acne			2	(1.4)
Vitiligo			2	(1.4)
Lichen sclerosus			1	(0.7)
Social circumstances				
Tobacco user	1	(1.4)		
Menopause			1	(0.7)
Surgical and medical procedures				
Appendicectomy	1	(1.4)		
Caesarean section	1	(1.4)		
Immune tolerance induction	1	(1.4)		
Osteosynthesis	1	(1.4)		
Cataract operation			1	(0.7)
Corneal transplant			1	(0.7)
Hip arthroplasty			1	(0.7)
Keratoplasty			1	(0.7)
Knee arthroplasty			1	(0.7)
Vascular disorders				
Hypertension	10	(13.9)	18	(12.2)
Raynaud's phenomenon	1	(1.4)		
Arteriosclerosis			1	(0.7)
Poor peripheral circulation			1	(0.7)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.6.102.3.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Analysis set				
N	54		105	
Blood and lymphatic system disorders				
Anaemia			7	(6.7)
Lymphadenopathy	1	(1.9)		
Cardiac disorders				
Bundle branch block right	1	(1.9)	3	(2.9)
Atrial fibrillation			2	(1.9)
Cardiac failure chronic			2	(1.9)
Atrioventricular block first degree	1	(1.9)		
Ventricular extrasystoles	1	(1.9)		
Angina pectoris			1	(1.0)
Bundle branch block left			1	(1.0)
Myocardial infarction			1	(1.0)
Congenital, familial and genetic disorders				
Congenital naevus	1	(1.9)		
Gilbert's syndrome	1	(1.9)		
Multiple lentigines syndrome	1	(1.9)		
Arrhythmogenic right ventricular dysplasia			1	(1.0)
Deafness congenital			1	(1.0)
Sickle cell trait			1	(1.0)
Tourette's disorder			1	(1.0)
Type V hyperlipidaemia			1	(1.0)
Ear and labyrinth disorders				
Deafness			2	(1.9)
Deafness bilateral	1	(1.9)	1	(1.0)
Deafness unilateral	1	(1.9)		
Vertigo positional	1	(1.9)		
Tinnitus			1	(1.0)
Endocrine disorders				
Hypothyroidism	3	(5.6)	5	(4.8)
Hyperthyroidism			1	(1.0)
Eye disorders				
Conjunctivitis allergic	12	(22.2)	15	(14.3)
Atopic keratoconjunctivitis			2	(1.9)
Myopia			2	(1.9)
Presbyopia			2	(1.9)
Visual impairment	1	(1.9)		
Blindness unilateral			1	(1.0)
Cataract			1	(1.0)
Ectropion			1	(1.0)
Eye pruritus			1	(1.0)
Keratoconus			1	(1.0)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	4	(7.4)	14	(13.3)
Dyspepsia	3	(5.6)	5	(4.8)
Gastritis	2	(3.7)	1	(1.0)
Constipation			3	(2.9)
Haemorrhoids			2	(1.9)
Irritable bowel syndrome	1	(1.9)	2	(1.9)
Colitis ulcerative	1	(1.9)	1	(1.0)
Dysphagia	1	(1.9)		
Pancreatic cyst	1	(1.9)		
Diverticulum			1	(1.0)
Large intestine polyp			1	(1.0)
Nausea			1	(1.0)
Stress ulcer			1	(1.0)

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Table 1.6.102.3.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Rest of World		
Gastrointestinal disorders		
Tooth malformation		1 (1.0)
General disorders and administration site conditions		
Pain		2 (1.9)
Asthenia		1 (1.0)
Peripheral swelling		1 (1.0)
Hepatobiliary disorders		
Cholelithiasis		1 (1.0)
Immune system disorders		
Seasonal allergy	22 (40.7)	47 (44.8)
Food allergy	20 (37.0)	38 (36.2)
Drug hypersensitivity	8 (14.8)	18 (17.1)
Hypersensitivity	6 (11.1)	14 (13.3)
Dust allergy		8 (7.6)
Allergy to animal	3 (5.6)	7 (6.7)
Multiple allergies	1 (1.9)	6 (5.7)
Allergy to chemicals		4 (3.8)
Allergy to metals	2 (3.7)	1 (1.0)
Allergy to plants		2 (1.9)
Milk allergy	1 (1.9)	2 (1.9)
Rubber sensitivity	1 (1.9)	2 (1.9)
Perfume sensitivity	1 (1.9)	
Allergy to arthropod sting		1 (1.0)
Iodine allergy		1 (1.0)
Infections and infestations		
Herpes simplex	3 (5.6)	4 (3.8)
Oral herpes	3 (5.6)	2 (1.9)
Rhinitis		2 (1.9)
Chronic sinusitis	1 (1.9)	1 (1.0)
Conjunctivitis	1 (1.9)	1 (1.0)
Hordeolum	1 (1.9)	
Folliculitis		1 (1.0)
Paronychia		1 (1.0)
Sinusitis		1 (1.0)
Tinea versicolour		1 (1.0)
Urinary tract infection		1 (1.0)
Injury, poisoning and procedural complications		
Foot fracture		1 (1.0)
Joint injury		1 (1.0)
Ligament sprain		1 (1.0)
Limb injury		1 (1.0)
Meniscus injury		1 (1.0)
Tendon injury		1 (1.0)
Tendon rupture		1 (1.0)
Tibia fracture		1 (1.0)
Ulnar nerve injury		1 (1.0)
Investigations		
Blood cholesterol increased	3 (5.6)	
Blood pressure increased	1 (1.9)	
Cardiac murmur	1 (1.9)	
Eosinophil count increased		1 (1.0)
Human papilloma virus test positive		1 (1.0)
Vitamin D decreased		1 (1.0)
Metabolism and nutrition disorders		
Type 2 diabetes mellitus	4 (7.4)	10 (9.5)
Hypercholesterolaemia	2 (3.7)	9 (8.6)
Hyperlipidaemia	2 (3.7)	

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Table 1.6.102.3.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Metabolism and nutrition disorders				
Hyperlipidaemia			7	(6.7)
Obesity	3	(5.6)	7	(6.7)
Gout	3	(5.6)	3	(2.9)
Hypertriglyceridaemia	1	(1.9)	4	(3.8)
Lactose intolerance			4	(3.8)
Gluten sensitivity			3	(2.9)
Diabetes mellitus			2	(1.9)
Decreased appetite	1	(1.9)		
Folate deficiency	1	(1.9)		
Vitamin D deficiency	1	(1.9)	1	(1.0)
Cow's milk intolerance			1	(1.0)
Hyperuricaemia			1	(1.0)
Hypoglycaemia			1	(1.0)
Hypokalaemia			1	(1.0)
Overweight			1	(1.0)
Musculoskeletal and connective tissue disorders				
Back pain	2	(3.7)	9	(8.6)
Osteoarthritis	3	(5.6)	8	(7.6)
Arthralgia	2	(3.7)	4	(3.8)
Intervertebral disc protrusion			3	(2.9)
Scoliosis			3	(2.9)
Arthritis			2	(1.9)
Rheumatoid arthritis			2	(1.9)
Fibromyalgia	1	(1.9)		
Intervertebral disc degeneration	1	(1.9)	1	(1.0)
Neck pain	1	(1.9)	1	(1.0)
Pain in extremity	1	(1.9)		
Plantar fasciitis	1	(1.9)	1	(1.0)
Psoriatic arthropathy	1	(1.9)		
Rotator cuff syndrome	1	(1.9)		
Bursitis			1	(1.0)
Joint swelling			1	(1.0)
Muscle spasms			1	(1.0)
Neuropathic arthropathy			1	(1.0)
Temporomandibular joint syndrome			1	(1.0)
Vertebral osteophyte			1	(1.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Seborrhoeic keratosis			3	(2.9)
Acoustic neuroma	1	(1.9)		
Haemangioma			1	(1.0)
Nervous system disorders				
Headache	1	(1.9)	9	(8.6)
Migraine	4	(7.4)	5	(4.8)
Carpal tunnel syndrome			2	(1.9)
Diabetic neuropathy			2	(1.9)
Cervical radiculopathy	1	(1.9)		
Delayed sleep phase			1	(1.0)
Dizziness			1	(1.0)
Migraine with aura			1	(1.0)
Seizure			1	(1.0)
Somnolence			1	(1.0)
Psychiatric disorders				
Depression	3	(5.6)	17	(16.2)
Anxiety	4	(7.4)	13	(12.4)
Insomnia	3	(5.6)	12	(11.4)
Anxiety disorder	2	(3.7)		
Attention deficit/hyperactivity disorder	1	(1.9)	3	(2.9)
Body dysmorphic disorder	1	(1.9)		
Generalised anxiety disorder	1	(1.9)		
Sleep disorder	1	(1.9)		

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Table 1.6.102.3.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Rest of World		
Psychiatric disorders		
Oppositional defiant disorder		1 (1.0)
Post-traumatic stress disorder		1 (1.0)
Social anxiety disorder		1 (1.0)
Renal and urinary disorders		
Chronic kidney disease	1 (1.9)	
Pollakiuria	1 (1.9)	
Renal cyst	1 (1.9)	1 (1.0)
Automatic bladder		1 (1.0)
Haematuria		1 (1.0)
Reproductive system and breast disorders		
Cervical dysplasia	1 (1.9)	
Erectile dysfunction	1 (1.9)	1 (1.0)
Pelvic congestion	1 (1.9)	
Benign prostatic hyperplasia		1 (1.0)
Dysmenorrhoea		1 (1.0)
Ovarian cyst		1 (1.0)
Respiratory, thoracic and mediastinal disorders		
Asthma	24 (44.4)	53 (50.5)
Rhinitis allergic	6 (11.1)	12 (11.4)
Chronic obstructive pulmonary disease	3 (5.6)	5 (4.8)
Sleep apnoea syndrome	1 (1.9)	4 (3.8)
Adenoidal hypertrophy		1 (1.0)
Dyspnoea		1 (1.0)
Lung cyst		1 (1.0)
Vocal cord dysfunction		1 (1.0)
Skin and subcutaneous tissue disorders		
Vitiligo	4 (7.4)	1 (1.0)
Acne		4 (3.8)
Pruritus	2 (3.7)	1 (1.0)
Actinic keratosis		2 (1.9)
Alopecia		2 (1.9)
Alopecia areata	1 (1.9)	2 (1.9)
Urticaria	1 (1.9)	2 (1.9)
Chronic spontaneous urticaria	1 (1.9)	1 (1.0)
Dermal cyst	1 (1.9)	1 (1.0)
Dermatitis contact	1 (1.9)	1 (1.0)
Dermatitis papillaris capillitii	1 (1.9)	
Dyshidrotic eczema	1 (1.9)	
Hyperkeratosis	1 (1.9)	
Neurodermatitis	1 (1.9)	1 (1.0)
Psoriasis	1 (1.9)	
Transient acantholytic dermatosis	1 (1.9)	
Acanthosis nigricans		1 (1.0)
Dry skin		1 (1.0)
Hidradenitis		1 (1.0)
Keratosis pilaris		1 (1.0)
Rosacea		1 (1.0)
Social circumstances		
Tobacco user	4 (7.4)	5 (4.8)
Postmenopause	3 (5.6)	2 (1.9)
Surgical and medical procedures		
Alcohol rehabilitation	1 (1.9)	
Heart valve replacement	1 (1.9)	1 (1.0)
Vasectomy	1 (1.9)	
Continuous positive airway pressure		1 (1.0)
Intra-uterine contraceptive device		1 (1.0)
Intra-uterine contraceptive device insertion		1 (1.0)

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Table 1.6.102.3.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Vascular disorders				
Hypertension	10	(18.5)	25	(23.8)
Peripheral vascular disorder			3	(2.9)
Lymphoedema	1	(1.9)		
Deep vein thrombosis			1	(1.0)

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Table 1.6.103.3.1: Total, Europe, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Europe				
Analysis set				
N	72		147	
Cardiac disorders				
Arrhythmia			1	(0.7)
Myocardial infarction			1	(0.7)
Pericarditis			1	(0.7)
Wolff-Parkinson-White syndrome			1	(0.7)
Congenital, familial and genetic disorders				
Cryptorchism	1	(1.4)		
Phimosis	1	(1.4)		
Eye disorders				
Atopic keratoconjunctivitis	2	(2.8)		
Blepharitis	1	(1.4)	1	(0.7)
Cataract	1	(1.4)		
Conjunctivitis allergic	1	(1.4)	1	(0.7)
Myopia	1	(1.4)	1	(0.7)
Retinal detachment	1	(1.4)		
Dry eye			1	(0.7)
Gastrointestinal disorders				
Inguinal hernia	2	(2.8)		
Chronic gastritis	1	(1.4)		
Haemorrhoids			1	(0.7)
General disorders and administration site conditions				
Inflammation			1	(0.7)
Hepatobiliary disorders				
Hepatitis			1	(0.7)
Immune system disorders				
Food allergy	1	(1.4)		
Seasonal allergy			2	(1.4)
Infections and infestations				
Eczema herpeticum	5	(6.9)	4	(2.7)
Erysipelas	2	(2.8)		
Conjunctivitis			3	(2.0)
Chronic sinusitis	1	(1.4)		
Gastrointestinal candidiasis	1	(1.4)		
Herpes simplex	1	(1.4)	1	(0.7)
Herpes virus infection	1	(1.4)		
Herpes zoster	1	(1.4)		
Impetigo	1	(1.4)		
Oral herpes	1	(1.4)		
Cellulitis			2	(1.4)
Furuncle			2	(1.4)
Ascariasis			1	(0.7)
Keratitis viral			1	(0.7)
Lyme disease			1	(0.7)
Neuroborreliosis			1	(0.7)
Otitis media			1	(0.7)
Papilloma viral infection			1	(0.7)
Pilonidal cyst			1	(0.7)
Sinusitis			1	(0.7)
Wound infection staphylococcal			1	(0.7)
Injury, poisoning and procedural complications				
Clavicle fracture	1	(1.4)		
Ligament rupture	1	(1.4)		
Radius fracture	1	(1.4)		

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Table 1.6.103.3.1: Total, Europe, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Europe		
Injury, poisoning and procedural complications		
Femoral neck fracture		1 (0.7)
Foot fracture		1 (0.7)
Jaw fracture		1 (0.7)
Upper limb fracture		1 (0.7)
Investigations		
Arthroscopy	1 (1.4)	
Blood pressure increased	1 (1.4)	
Blood creatinine increased		1 (0.7)
Smear cervix		1 (0.7)
Metabolism and nutrition disorders		
Hypercholesterolaemia	1 (1.4)	
Protein deficiency	1 (1.4)	
Musculoskeletal and connective tissue disorders		
Intervertebral disc protrusion	1 (1.4)	1 (0.7)
Juvenile idiopathic arthritis	1 (1.4)	
Osteochondrosis		1 (0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Acanthoma	1 (1.4)	
Cervix carcinoma	1 (1.4)	
Haemangioma	1 (1.4)	
Anogenital warts		1 (0.7)
Nervous system disorders		
Cerebrovascular accident	1 (1.4)	1 (0.7)
Hydrocephalus	1 (1.4)	
Alcoholic seizure		1 (0.7)
Facial paresis		1 (0.7)
Pregnancy, puerperium and perinatal conditions		
Gestational hypertension		1 (0.7)
Psychiatric disorders		
Depression	2 (2.8)	3 (2.0)
Alcohol problem		1 (0.7)
Depressed mood		1 (0.7)
Renal and urinary disorders		
Glomerulonephritis		1 (0.7)
Nephrolithiasis		1 (0.7)
Reproductive system and breast disorders		
Testicular retraction	1 (1.4)	
Respiratory, thoracic and mediastinal disorders		
Asthma	2 (2.8)	4 (2.7)
Nasal inflammation	1 (1.4)	
Nasal polyps	1 (1.4)	
Skin and subcutaneous tissue disorders		
Urticaria	2 (2.8)	1 (0.7)
Neurodermatitis	1 (1.4)	
Dermatitis contact		1 (0.7)
Dyshidrotic eczema		1 (0.7)
Eczema		1 (0.7)
Hypersensitivity vasculitis		1 (0.7)
Papulopustular rosacea		1 (0.7)
Surgical and medical procedures		
Appendicectomy	3 (4.2)	

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Table 1.6.103.3.1: Total, Europe, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Europe				
Surgical and medical procedures				
Appendicectomy			6	(4.1)
Tonsillectomy	3	(4.2)	3	(2.0)
Caesarean section	1	(1.4)	5	(3.4)
Corneal transplant	2	(2.8)		
Hysterectomy	2	(2.8)	1	(0.7)
Knee operation	2	(2.8)	2	(1.4)
Cardiac ablation			3	(2.0)
Cholecystectomy			3	(2.0)
Arthrodesis	1	(1.4)		
Cataract operation	1	(1.4)		
Circumcision	1	(1.4)	1	(0.7)
Endodontic procedure	1	(1.4)		
Eye operation	1	(1.4)		
Haemorrhoid operation	1	(1.4)		
Keratoplasty	1	(1.4)		
Laser therapy	1	(1.4)		
Ligament operation	1	(1.4)	1	(0.7)
Muscle operation	1	(1.4)		
Nasal operation	1	(1.4)		
Plastic surgery	1	(1.4)		
Salpingo-oophorectomy	1	(1.4)		
Skin neoplasm excision	1	(1.4)		
Spinal decompression	1	(1.4)		
Steroid therapy	1	(1.4)		
Turbinoplasty	1	(1.4)		
Wisdom teeth removal	1	(1.4)		
Nasal polypectomy			2	(1.4)
Strabismus correction			2	(1.4)
Toe operation			2	(1.4)
Adenoidectomy			1	(0.7)
Balneotherapy			1	(0.7)
Brain lobectomy			1	(0.7)
Carotid artery bypass			1	(0.7)
Carpal tunnel decompression			1	(0.7)
Eyelid operation			1	(0.7)
Foot operation			1	(0.7)
Hepatitis B immunisation			1	(0.7)
Hepatitis immunisation			1	(0.7)
Hernia repair			1	(0.7)
Immunisation			1	(0.7)
Inguinal hernia repair			1	(0.7)
Intervertebral disc operation			1	(0.7)
Intraocular lens implant			1	(0.7)
Limb operation			1	(0.7)
Myopia correction			1	(0.7)
Osteosynthesis			1	(0.7)
Otoplasty			1	(0.7)
Renal stone removal			1	(0.7)
Stent placement			1	(0.7)
Vascular disorders				
Kawasaki's disease	1	(1.4)		

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Table 1.6.103.3.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Analysis set				
N	54		105	
Blood and lymphatic system disorders				
Dermatopathic lymphadenopathy	1	(1.9)		
Iron deficiency anaemia	1	(1.9)		
Cardiac disorders				
Myocardial infarction			2	(1.9)
Congenital, familial and genetic disorders				
Ventricular septal defect	1	(1.9)		
Ear and labyrinth disorders				
Ear disorder	1	(1.9)		
Eye disorders				
Cataract	1	(1.9)	4	(3.8)
Conjunctivitis allergic	2	(3.7)		
Keratoconus	1	(1.9)		
Retinal detachment			1	(1.0)
Strabismus			1	(1.0)
Gastrointestinal disorders				
Haemorrhoids	2	(3.7)	1	(1.0)
Inguinal hernia			2	(1.9)
Abdominal adhesions			1	(1.0)
Abdominal hernia			1	(1.0)
Colitis			1	(1.0)
Gastrooesophageal reflux disease			1	(1.0)
Gingival recession			1	(1.0)
Lumbar hernia			1	(1.0)
Oesophagitis			1	(1.0)
Peptic ulcer			1	(1.0)
Rectal prolapse			1	(1.0)
Umbilical hernia			1	(1.0)
General disorders and administration site conditions				
Chest pain			1	(1.0)
Cyst			1	(1.0)
Fatigue			1	(1.0)
Hepatobiliary disorders				
Cholecystitis	1	(1.9)	2	(1.9)
Hepatic steatosis			1	(1.0)
Immune system disorders				
Food allergy	2	(3.7)	3	(2.9)
Allergy to animal			2	(1.9)
Seasonal allergy			2	(1.9)
Drug hypersensitivity			1	(1.0)
Infections and infestations				
Impetigo	3	(5.6)	7	(6.7)
Appendicitis	1	(1.9)	4	(3.8)
Staphylococcal skin infection	2	(3.7)		
Herpes zoster	1	(1.9)	3	(2.9)
Tonsillitis			3	(2.9)
Herpes simplex	1	(1.9)	2	(1.9)
Oral herpes	1	(1.9)	2	(1.9)
Sinusitis			2	(1.9)
Staphylococcal infection	1	(1.9)	2	(1.9)
Bronchitis	1	(1.9)	1	(1.0)
Cellulitis	1	(1.9)		

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Table 1.6.103.3.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Rest of World		
Infections and infestations		
Eczema herpeticum	1 (1.9)	
Fungal infection	1 (1.9)	
Measles	1 (1.9)	
Molluscum contagiosum	1 (1.9)	
Osteomyelitis	1 (1.9)	
Peritonsillitis	1 (1.9)	
Poliomyelitis	1 (1.9)	
Varicella	1 (1.9)	
Abscess limb		1 (1.0)
Acarodermatitis		1 (1.0)
Acne pustular		1 (1.0)
Acute sinusitis		1 (1.0)
Adenoiditis		1 (1.0)
Body tinea		1 (1.0)
Chronic tonsillitis		1 (1.0)
Clostridium difficile colitis		1 (1.0)
Conjunctivitis bacterial		1 (1.0)
Croup infectious		1 (1.0)
Dermatitis infected		1 (1.0)
External ear cellulitis		1 (1.0)
Kidney infection		1 (1.0)
Oesophageal candidiasis		1 (1.0)
Pneumonia		1 (1.0)
Tinea cruris		1 (1.0)
Tinea pedis		1 (1.0)
Urinary tract infection bacterial		1 (1.0)
Viral upper respiratory tract infection		1 (1.0)
Vulvovaginal mycotic infection		1 (1.0)
Injury, poisoning and procedural complications		
Foot fracture	2 (3.7)	
Wrist fracture	2 (3.7)	
Ligament rupture		2 (1.9)
Cartilage injury	1 (1.9)	
Fall	1 (1.9)	
Hand fracture	1 (1.9)	
Arthropod bite		1 (1.0)
Clavicle fracture		1 (1.0)
Concussion		1 (1.0)
Injury		1 (1.0)
Meniscus injury		1 (1.0)
Upper limb fracture		1 (1.0)
Investigations		
Colonoscopy	1 (1.9)	2 (1.9)
Arthroscopy	1 (1.9)	1 (1.0)
Endoscopy upper gastrointestinal tract	1 (1.9)	
Catheterisation cardiac		1 (1.0)
Endoscopy		1 (1.0)
Hysteroscopy		1 (1.0)
Laparoscopy		1 (1.0)
Metabolism and nutrition disorders		
Hypercholesterolaemia		1 (1.0)
Type 2 diabetes mellitus		1 (1.0)
Musculoskeletal and connective tissue disorders		
Arthralgia	1 (1.9)	1 (1.0)
Limb mass	1 (1.9)	
Rotator cuff syndrome	1 (1.9)	
Back pain		1 (1.0)
Exostosis		1 (1.0)
Pain in extremity		1 (1.0)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.6.103.3.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Basal cell carcinoma	1	(1.9)	1	(1.0)
Haemangioma	1	(1.9)		
Meningioma	1	(1.9)		
Colon cancer			1	(1.0)
Dysplastic naevus			1	(1.0)
Lip squamous cell carcinoma			1	(1.0)
Osteochondroma			1	(1.0)
Skin papilloma			1	(1.0)
Nervous system disorders				
Migraine			2	(1.9)
Cerebrovascular accident	1	(1.9)		
Trigeminal neuralgia	1	(1.9)		
Headache			1	(1.0)
Sciatica			1	(1.0)
Pregnancy, puerperium and perinatal conditions				
Abortion			1	(1.0)
Abortion spontaneous			1	(1.0)
Ectopic pregnancy			1	(1.0)
Psychiatric disorders				
Depression	1	(1.9)	2	(1.9)
Anxiety			1	(1.0)
Drug use disorder			1	(1.0)
Renal and urinary disorders				
Nephrolithiasis			1	(1.0)
Reproductive system and breast disorders				
Menorrhagia	1	(1.9)		
Cervical dysplasia			1	(1.0)
Dysmenorrhoea			1	(1.0)
Ovarian cyst			1	(1.0)
Ovarian cyst ruptured			1	(1.0)
Uterine polyp			1	(1.0)
Respiratory, thoracic and mediastinal disorders				
Asthma	4	(7.4)	10	(9.5)
Nasal septum deviation	2	(3.7)		
Dyspnoea			1	(1.0)
Sleep apnoea syndrome			1	(1.0)
Skin and subcutaneous tissue disorders				
Acne	1	(1.9)	1	(1.0)
Dyshidrotic eczema			1	(1.0)
Psoriasis			1	(1.0)
Rosacea			1	(1.0)
Urticaria			1	(1.0)
Social circumstances				
Infant			1	(1.0)
Postmenopause			1	(1.0)
Surgical and medical procedures				
Tonsillectomy	1	(1.9)	9	(8.6)
Appendicectomy	2	(3.7)	7	(6.7)
Hysterectomy	2	(3.7)	6	(5.7)
Female sterilisation	3	(5.6)	4	(3.8)
Caesarean section			5	(4.8)
Cholecystectomy	1	(1.9)	5	(4.8)
Cataract operation			4	(3.8)
Eye operation	2	(3.7)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.6.103.3.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Rest of World		
Surgical and medical procedures		
Haemorrhoid operation	2 (3.7)	1 (1.0)
Nasal septal operation	2 (3.7)	1 (1.0)
Wisdom teeth removal	2 (3.7)	2 (1.9)
Salpingectomy		3 (2.9)
Vasectomy	1 (1.9)	3 (2.9)
Aortic bypass		2 (1.9)
Endometrial ablation	1 (1.9)	2 (1.9)
Explorative laparotomy		2 (1.9)
Foot operation		2 (1.9)
Inguinal hernia repair		2 (1.9)
Nasal operation		2 (1.9)
Renal stone removal		2 (1.9)
Spinal operation		2 (1.9)
Craniotomy	1 (1.9)	
Cyst removal	1 (1.9)	
Gastric bypass	1 (1.9)	1 (1.0)
Heart valve replacement	1 (1.9)	
Knee operation	1 (1.9)	1 (1.0)
Mammoplasty	1 (1.9)	
Metabolic surgery	1 (1.9)	
Open reduction of fracture	1 (1.9)	
Skin neoplasm excision	1 (1.9)	1 (1.0)
Spinal fusion surgery	1 (1.9)	1 (1.0)
Transfusion	1 (1.9)	
Uterine dilation and curettage	1 (1.9)	1 (1.0)
Abdominal hernia repair		1 (1.0)
Adenoidectomy		1 (1.0)
Adenotonsillectomy		1 (1.0)
Angioplasty		1 (1.0)
Ankle arthroplasty		1 (1.0)
Ankle operation		1 (1.0)
Bone lesion excision		1 (1.0)
Bone operation		1 (1.0)
Cardiac resynchronisation therapy		1 (1.0)
Carpal tunnel decompression		1 (1.0)
Colectomy		1 (1.0)
Endodontic procedure		1 (1.0)
Eye laser surgery		1 (1.0)
Fracture treatment		1 (1.0)
Gingival graft		1 (1.0)
Hernia hiatus repair		1 (1.0)
Hernia repair		1 (1.0)
Implantable defibrillator insertion		1 (1.0)
In vitro fertilisation		1 (1.0)
Incisional drainage		1 (1.0)
Intraocular lens implant		1 (1.0)
Keratomileusis		1 (1.0)
Ligament operation		1 (1.0)
Limb operation		1 (1.0)
Lithotripsy		1 (1.0)
Meniscus operation		1 (1.0)
Myomectomy		1 (1.0)
Oesophagogastric fundoplasty		1 (1.0)
Oophorectomy		1 (1.0)
Oral surgery		1 (1.0)
Ovarian cystectomy		1 (1.0)
Papilloma excision		1 (1.0)
Peritoneal adhesions division		1 (1.0)
Phototherapy		1 (1.0)
Rectal prolapse repair		1 (1.0)
Rhinoplasty		1 (1.0)
Sinus operation		1 (1.0)
Skin graft		1 (1.0)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.6.103.3.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Rest of World		
Surgical and medical procedures		
Spinal laminectomy		1 (1.0)
Splenectomy		1 (1.0)
Strabismus correction		1 (1.0)
Tenoplasty		1 (1.0)
Umbilical hernia repair		1 (1.0)
Uvulectomy		1 (1.0)
Vascular disorders		
Hypertension		1 (1.0)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.6.104.3.1: Total, Europe, Atopy history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	147 (100.0)	72 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	42 (28.6)	14 (19.4)
1-3	17 (11.6)	4 (5.6)
More than 3	25 (17.0)	10 (13.9)
Never	81 (55.1)	48 (66.7)
Past	22 (15.0)	7 (9.7)
1-3	15 (10.2)	3 (4.2)
More than 3	7 (4.8)	4 (5.6)
Unknown	2 (1.4)	3 (4.2)
ASTHMA		
Current	66 (44.9)	34 (47.2)
Never	65 (44.2)	29 (40.3)
Past	16 (10.9)	9 (12.5)
ATOPIC KERATOCONJUNCTIVITIS		
Current	6 (4.1)	5 (6.9)
1-3	5 (3.4)	1 (1.4)
More than 3	1 (0.7)	4 (5.6)
Never	136 (92.5)	59 (81.9)
Past	2 (1.4)	4 (5.6)
1-3	2 (1.4)	3 (4.2)
More than 3		1 (1.4)
Unknown	3 (2.0)	4 (5.6)
ECZEMA HERPETICUM		
Current	1 (0.7)	1 (1.4)
1-3	1 (0.7)	
More than 3		1 (1.4)
Never	120 (81.6)	62 (86.1)
Past	23 (15.6)	7 (9.7)
1-3	18 (12.2)	6 (8.3)
More than 3	5 (3.4)	1 (1.4)
Unknown	3 (2.0)	2 (2.8)
FOOD ALLERGY		
Current	48 (32.7)	27 (37.5)
Never	86 (58.5)	39 (54.2)
Past	7 (4.8)	2 (2.8)
Unknown	6 (4.1)	4 (5.6)
HAY FEVER		
Current	86 (58.5)	43 (59.7)
Never	46 (31.3)	24 (33.3)
Past	13 (8.8)	3 (4.2)
Unknown	2 (1.4)	2 (2.8)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.6.104.3.1: Total, Rest of World, Atopy history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	105 (100.0)	54 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	16 (15.2)	12 (22.2)
1-3	4 (3.8)	2 (3.7)
More than 3	12 (11.4)	10 (18.5)
Never	67 (63.8)	34 (63.0)
Past	12 (11.4)	4 (7.4)
1-3	6 (5.7)	3 (5.6)
More than 3	6 (5.7)	1 (1.9)
Unknown	10 (9.5)	4 (7.4)
ASTHMA		
Current	53 (50.5)	24 (44.4)
Never	39 (37.1)	21 (38.9)
Past	12 (11.4)	9 (16.7)
Unknown	1 (1.0)	
ATOPIC KERATOCONJUNCTIVITIS		
Current	2 (1.9)	
1-3	1 (1.0)	
More than 3	1 (1.0)	
Never	92 (87.6)	51 (94.4)
Unknown	11 (10.5)	3 (5.6)
ECZEMA HERPETICUM		
Never	98 (93.3)	50 (92.6)
Past		2 (3.7)
1-3		2 (3.7)
Unknown	7 (6.7)	2 (3.7)
FOOD ALLERGY		
Current	41 (39.0)	21 (38.9)
Never	59 (56.2)	30 (55.6)
Past	2 (1.9)	1 (1.9)
Unknown	3 (2.9)	2 (3.7)
HAY FEVER		
Current	55 (52.4)	25 (46.3)
Never	42 (40.0)	27 (50.0)
Past	4 (3.8)	
Unknown	4 (3.8)	2 (3.7)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.6.105.3.1: Total, Europe, Skin disease history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	147 (100.0)	72 (100.0)
ALOPECIA		
Current	6 (4.1)	7 (9.7)
Never	137 (93.2)	64 (88.9)
Past	3 (2.0)	
Unknown	1 (0.7)	1 (1.4)
CELLULITIS		
Never	140 (95.2)	69 (95.8)
Past	4 (2.7)	3 (4.2)
1-3	4 (2.7)	3 (4.2)
Unknown	3 (2.0)	
HERPES SIMPLEX		
Current	8 (5.4)	4 (5.6)
1-3	3 (2.0)	
More than 3	5 (3.4)	4 (5.6)
Never	99 (67.3)	57 (79.2)
Past	37 (25.2)	10 (13.9)
1-3	21 (14.3)	7 (9.7)
More than 3	16 (10.9)	3 (4.2)
Unknown	3 (2.0)	1 (1.4)
IMPETIGO		
Never	122 (83.0)	63 (87.5)
Past	18 (12.2)	8 (11.1)
1-3	12 (8.2)	5 (6.9)
More than 3	6 (4.1)	3 (4.2)
Unknown	7 (4.8)	1 (1.4)
OTHER SKIN INFECTIONS		
Never	132 (89.8)	60 (83.3)
Past	12 (8.2)	8 (11.1)
Unknown	3 (2.0)	4 (5.6)
VITILIGO		
Current	2 (1.4)	
Never	143 (97.3)	72 (100.0)
Past	1 (0.7)	
Unknown	1 (0.7)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.6.105.3.1: Total, Rest of World, Skin disease history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	105 (100.0)	54 (100.0)
ALOPECIA		
Current	4 (3.8)	1 (1.9)
Never	100 (95.2)	51 (94.4)
Past	1 (1.0)	1 (1.9)
Unknown		1 (1.9)
CELLULITIS		
Never	95 (90.5)	49 (90.7)
Past	8 (7.6)	3 (5.6)
1-3	7 (6.7)	2 (3.7)
More than 3	1 (1.0)	1 (1.9)
Unknown	2 (1.9)	2 (3.7)
HERPES SIMPLEX		
Current	3 (2.9)	4 (7.4)
1-3	2 (1.9)	2 (3.7)
More than 3	1 (1.0)	2 (3.7)
Never	86 (81.9)	42 (77.8)
Past	14 (13.3)	7 (13.0)
1-3	11 (10.5)	5 (9.3)
More than 3	3 (2.9)	2 (3.7)
Unknown	2 (1.9)	1 (1.9)
IMPETIGO		
Never	79 (75.2)	44 (81.5)
Past	20 (19.0)	5 (9.3)
1-3	16 (15.2)	4 (7.4)
More than 3	4 (3.8)	1 (1.9)
Unknown	6 (5.7)	5 (9.3)
OTHER SKIN INFECTIONS		
Never	84 (80.0)	43 (79.6)
Past	15 (14.3)	6 (11.1)
Unknown	6 (5.7)	5 (9.3)
VITILIGO		
Current	1 (1.0)	4 (7.4)
Never	104 (99.0)	50 (92.6)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.6.107.3.1: Total, Europe, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	147 (100.0)	72 (100.0)
Antibiotics		
Yes	66 (44.9)	23 (31.9)
No	77 (52.4)	47 (65.3)
Unknown	4 (2.7)	2 (2.8)
Azathioprine		
Yes	12 (8.2)	10 (13.9)
More than 12 weeks?		
Yes	5 (3.4)	7 (9.7)
No	4 (2.7)	2 (2.8)
Unknown	3 (2.0)	1 (1.4)
Reason for discontinuation		
Inadequate efficacy	8 (5.4)	8 (11.1)
Other	1 (0.7)	
Side effects	3 (2.0)	2 (2.8)
No	132 (89.8)	62 (86.1)
Reason for not using		
Risk of side effects	13 (8.8)	10 (13.9)
Other	119 (81.0)	52 (72.2)
Unknown	3 (2.0)	
Calcineurin inhibitors		
Yes	92 (62.6)	47 (65.3)
No	47 (32.0)	23 (31.9)
Unknown	7 (4.8)	2 (2.8)
Cyclosporine		
Yes	69 (46.9)	37 (51.4)
More than 12 weeks?		
Yes	59 (40.1)	30 (41.7)
No	8 (5.4)	4 (5.6)
Unknown	2 (1.4)	3 (4.2)
Reason for discontinuation		
Inadequate efficacy	39 (26.5)	15 (20.8)
Other	11 (7.5)	12 (16.7)
Side effects	19 (12.9)	10 (13.9)
No	77 (52.4)	35 (48.6)
Reason for not using		
Contraindications	12 (8.2)	2 (2.8)
Risk of side effects	20 (13.6)	13 (18.1)
Other	45 (30.6)	20 (27.8)
Unknown	1 (0.7)	
Methotrexate		
Yes	18 (12.2)	17 (23.6)
More than 12 weeks?		
Yes	11 (7.5)	9 (12.5)
No	4 (2.7)	5 (6.9)
Unknown	3 (2.0)	3 (4.2)
Reason for discontinuation		
Inadequate efficacy	6 (4.1)	7 (9.7)
Other	7 (4.8)	8 (11.1)
Side effects	5 (3.4)	2 (2.8)
No	125 (85.0)	54 (75.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.6.107.3.1: Total, Europe, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Reason for not using		
Contraindications	1 (0.7)	
Risk of side effects	10 (6.8)	7 (9.7)
Other	114 (77.6)	47 (65.3)
Unknown	4 (2.7)	1 (1.4)
Monoclonal antibody/Dupilumab		
Yes	6 (4.1)	4 (5.6)
No	140 (95.2)	67 (93.1)
Unknown		1 (1.4)
Mycophenolate		
Yes	5 (3.4)	3 (4.2)
More than 12 weeks?		
Yes	1 (0.7)	
No	1 (0.7)	1 (1.4)
Unknown	3 (2.0)	2 (2.8)
Reason for discontinuation		
Inadequate efficacy	1 (0.7)	3 (4.2)
Other	1 (0.7)	
Side effects	2 (1.4)	
No	134 (91.2)	68 (94.4)
Reason for not using		
Risk of side effects	12 (8.2)	10 (13.9)
Other	122 (83.0)	58 (80.6)
Unknown	8 (5.4)	1 (1.4)
Other immunosuppressant		
Yes	4 (2.7)	
No	140 (95.2)	71 (98.6)
Unknown	3 (2.0)	1 (1.4)
Phototherapy		
Yes	97 (66.0)	37 (51.4)
No	49 (33.3)	35 (48.6)
Unknown	1 (0.7)	
Systemic steroids		
Yes	88 (59.9)	53 (73.6)
No	55 (37.4)	19 (26.4)
Unknown	4 (2.7)	
Topical corticosteroids		
Yes	145 (98.6)	68 (94.4)
Highest potency		
High	80 (54.4)	31 (43.1)
Low	4 (2.7)	
Moderate	20 (13.6)	16 (22.2)
Ultra high	34 (23.1)	21 (29.2)
Unknown	7 (4.8)	
No	2 (1.4)	4 (5.6)
Wet wraps		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.6.107.3.1: Total, Europe, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	21 (14.3)	5 (6.9)
No	121 (82.3)	63 (87.5)
Unknown	5 (3.4)	4 (5.6)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.6.107.3.1: Total, Rest of World, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	105 (100.0)	54 (100.0)
Antibiotics		
Yes	41 (39.0)	21 (38.9)
No	61 (58.1)	27 (50.0)
Unknown	3 (2.9)	6 (11.1)
Azathioprine		
Yes	1 (1.0)	2 (3.7)
More than 12 weeks?		
Yes		1 (1.9)
No	1 (1.0)	
Unknown		1 (1.9)
Reason for discontinuation		
Inadequate efficacy	1 (1.0)	1 (1.9)
Other		1 (1.9)
No	102 (97.1)	50 (92.6)
Reason for not using		
Contraindications	3 (2.9)	2 (3.7)
Risk of side effects	14 (13.3)	6 (11.1)
Other	85 (81.0)	42 (77.8)
Unknown	2 (1.9)	2 (3.7)
Calcineurin inhibitors		
Yes	35 (33.3)	21 (38.9)
No	67 (63.8)	31 (57.4)
Unknown	3 (2.9)	2 (3.7)
Cyclosporine		
Yes	6 (5.7)	5 (9.3)
More than 12 weeks?		
Yes	1 (1.0)	4 (7.4)
No	5 (4.8)	
Unknown		1 (1.9)
Reason for discontinuation		
Inadequate efficacy	3 (2.9)	4 (7.4)
Other	2 (1.9)	
Side effects		1 (1.9)
No	91 (86.7)	44 (81.5)
Reason for not using		
Contraindications	3 (2.9)	1 (1.9)
Risk of side effects	30 (28.6)	17 (31.5)
Other	58 (55.2)	26 (48.1)
Unknown	8 (7.6)	5 (9.3)
Methotrexate		
Yes	11 (10.5)	13 (24.1)
More than 12 weeks?		
Yes	5 (4.8)	4 (7.4)
No	1 (1.0)	4 (7.4)
Unknown	5 (4.8)	5 (9.3)
Reason for discontinuation		
Inadequate efficacy	5 (4.8)	4 (7.4)
Other	5 (4.8)	6 (11.1)
Side effects	1 (1.0)	3 (5.6)
No	91 (86.7)	41 (75.9)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.6.107.3.1: Total, Rest of World, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Reason for not using		
Contraindications	3 (2.9)	2 (3.7)
Risk of side effects	9 (8.6)	3 (5.6)
Other	79 (75.2)	36 (66.7)
Unknown	3 (2.9)	
Monoclonal antibody/Dupilumab		
Yes	8 (7.6)	6 (11.1)
No	95 (90.5)	47 (87.0)
Unknown	2 (1.9)	1 (1.9)
Mycophenolate		
Yes	2 (1.9)	2 (3.7)
More than 12 weeks?		
Yes	1 (1.0)	1 (1.9)
No	1 (1.0)	1 (1.9)
Reason for discontinuation		
Inadequate efficacy	2 (1.9)	1 (1.9)
Other		1 (1.9)
No	101 (96.2)	48 (88.9)
Reason for not using		
Contraindications	3 (2.9)	2 (3.7)
Risk of side effects	13 (12.4)	6 (11.1)
Other	85 (81.0)	40 (74.1)
Unknown	2 (1.9)	4 (7.4)
Other immunosuppressant		
Yes	2 (1.9)	
No	101 (96.2)	50 (92.6)
Unknown	2 (1.9)	4 (7.4)
Phototherapy		
Yes	25 (23.8)	15 (27.8)
No	76 (72.4)	38 (70.4)
Unknown	4 (3.8)	1 (1.9)
Systemic steroids		
Yes	59 (56.2)	32 (59.3)
No	45 (42.9)	18 (33.3)
Unknown	1 (1.0)	4 (7.4)
Topical corticosteroids		
Yes	105 (100.0)	53 (98.1)
Highest potency		
High	51 (48.6)	26 (48.1)
Low	2 (1.9)	1 (1.9)
Moderate	28 (26.7)	13 (24.1)
Ultra high	21 (20.0)	8 (14.8)
Unknown	3 (2.9)	5 (9.3)
No		1 (1.9)
Wet wraps		
Yes	13 (12.4)	10 (18.5)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.6.107.3.1: Total, Rest of World, Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	85 (81.0)	42 (77.8)
Unknown	7 (6.7)	2 (3.7)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.6.205.3.1: Total, Region, EASI 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	141 (56.0)	20.2 (9.77;30.56)	1.6 (1.21; 2.03)	2.3 (1.46; 3.53)	0.0002	0.9148
Placebo + TCS	126	45 (35.7)					
Europe							
Tralokinumab Q2W + TCS	147	80 (54.4)	19.6 (5.94;33.19)	1.6 (1.10; 2.22)	2.2 (1.25; 4.01)	0.0066	
Placebo + TCS	72	25 (34.7)					
Rest of World							
Tralokinumab Q2W + TCS	105	61 (58.1)	21.0 (4.90;37.04)	1.6 (1.07; 2.30)	2.3 (1.19; 4.55)	0.0123	
Placebo + TCS	54	20 (37.0)					

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 1.6.206.3.1: Total, Region, EASI 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	83 (32.9)	11.4 (2.13;20.71)	1.5 (1.05; 2.25)	1.8 (1.08; 2.92)	0.0216	0.8078
Placebo + TCS	126	27 (21.4)					
Europe							
Tralokinumab Q2W + TCS	147	49 (33.3)	12.4 (0.22;24.56)	1.6 (0.96; 2.66)	1.9 (0.97; 3.62)	0.0590	
Placebo + TCS	72	15 (20.8)					
Rest of World							
Tralokinumab Q2W + TCS	105	34 (32.4)	10.1 (-4.27;24.48)	1.5 (0.82; 2.58)	1.7 (0.78; 3.53)	0.1847	
Placebo + TCS	54	12 (22.2)					

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 1.6.209.3.1: Total, Region, SCORAD 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	60 (23.8)	11.1 (3.16;18.98)	1.9 (1.12; 3.12)	2.1 (1.17; 3.84)	0.0117	0.2492
Placebo + TCS	126	16 (12.7)					
Europe							
Tralokinumab Q2W + TCS	147	36 (24.5)	14.7 (4.95;24.46)	2.5 (1.17; 5.38)	3.0 (1.26; 7.13)	0.0104	
Placebo + TCS	72	7 (9.7)					
Rest of World							
Tralokinumab Q2W + TCS	105	24 (22.9)	6.2 (-6.84;19.16)	1.4 (0.68; 2.75)	1.5 (0.63; 3.37)	0.3669	
Placebo + TCS	54	9 (16.7)					

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.

Table 1.6.210.3.1: Total, Region, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	249	115 (46.2)	9.7 (-0.74;20.16)	1.3 (0.97; 1.65)	1.5 (0.96; 2.32)	0.0738	0.8231
Placebo + TCS	126	46 (36.5)					
Europe							
Tralokinumab Q2W + TCS	145	70 (48.3)	10.9 (-2.88;24.72)	1.3 (0.92; 1.82)	1.6 (0.88; 2.80)	0.1290	
Placebo + TCS	72	27 (37.5)					
Rest of World							
Tralokinumab Q2W + TCS	104	45 (43.3)	8.1 (-7.93;24.08)	1.2 (0.80; 1.88)	1.4 (0.71; 2.75)	0.3297	
Placebo + TCS	54	19 (35.2)					

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 1.6.211.3.1: Total, Region, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	251	153 (61.0)	17.4 (6.78;27.98)	1.4 (1.12; 1.74)	2.0 (1.30; 3.10)	0.0014	0.4485
Placebo + TCS	126	55 (43.7)					
Europe							
Tralokinumab Q2W + TCS	146	89 (61.0)	13.9 (-0.07;27.94)	1.3 (0.98; 1.71)	1.8 (0.99; 3.11)	0.0516	
Placebo + TCS	72	34 (47.2)					
Rest of World							
Tralokinumab Q2W + TCS	105	64 (61.0)	22.0 (5.89;38.17)	1.6 (1.08; 2.26)	2.4 (1.24; 4.71)	0.0087	
Placebo + TCS	54	21 (38.9)					

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 1.6.213.3.1: Total, Region, POEM improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	250	199 (79.6)	16.2 (6.28;26.17)	1.3 (1.08; 1.46)	2.2 (1.38; 3.58)	0.0008	0.7845
Placebo + TCS	123	78 (63.4)					
Europe							
Tralokinumab Q2W + TCS	146	117 (80.1)	17.5 (4.41;30.50)	1.3 (1.05; 1.56)	2.4 (1.28; 4.53)	0.0060	
Placebo + TCS	70	44 (62.9)					
Rest of World							
Tralokinumab Q2W + TCS	104	82 (78.8)	14.6 (-0.80;29.94)	1.2 (0.98; 1.54)	2.0 (0.98; 4.13)	0.0505	
Placebo + TCS	53	34 (64.2)					

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.

Table 1.6.215.3.1: Total, Region, DLQI 0/1, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	62 (24.6)	12.7 (4.92;20.47)	2.1 (1.23; 3.47)	2.4 (1.31; 4.43)	0.0040	0.3128
Placebo + TCS	126	15 (11.9)					
Europe							
Tralokinumab Q2W + TCS	147	34 (23.1)	9.2 (-1.27;19.75)	1.7 (0.87; 3.17)	1.9 (0.86; 4.02)	0.1106	
Placebo + TCS	72	10 (13.9)					
Rest of World							
Tralokinumab Q2W + TCS	105	28 (26.7)	17.4 (5.93;28.82)	2.9 (1.18; 7.00)	3.6 (1.29; 9.90)	0.0109	
Placebo + TCS	54	5 (9.3)					

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 1.6.273.3.1: Total, Region, SCORAD 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	21 (8.3)	2.0 (-3.46; 7.39)	1.3 (0.60; 2.85)	1.3 (0.57; 3.14)	0.4989	0.4995
Placebo + TCS	126	8 (6.3)					
Europe							
Tralokinumab Q2W + TCS	147	11 (7.5)	3.3 (-3.02; 9.53)	1.8 (0.51; 6.14)	1.8 (0.50; 6.83)	0.3556	
Placebo + TCS	72	3 (4.2)					
Rest of World							
Tralokinumab Q2W + TCS	105	10 (9.5)	0.2 (-9.29; 9.70)	1.0 (0.37; 2.81)	1.0 (0.33; 3.19)	0.9663	
Placebo + TCS	54	5 (9.3)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

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Table 1.6.276.3.1: Total, Region, Atopic dermatitis flares, all observed data, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	75.03	70 (27.8)	119	158.60	130.5	187.5	0.0868
Placebo + TCS	126	37.94	43 (34.1)	75	197.67	155.0	244.4	0.0868
Europe								
Tralokinumab Q2W + TCS	147	44.14	39 (26.5)	67	151.79	118.4	191.5	
Placebo + TCS	72	21.50	28 (38.9)	50	232.52	173.7	303.3	
Rest of World								
Tralokinumab Q2W + TCS	105	30.89	31 (29.5)	52	168.32	125.3	217.4	
Placebo + TCS	54	16.44	15 (27.8)	25	152.09	100.7	221.6	

The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. 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. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.6.277.3.1: Total, Region, Atopic dermatitis flares, excluding data after rescue medication, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	74.09	69 (27.4)	113	152.51	125.2	181.5	0.0555
Placebo + TCS	126	35.55	40 (31.7)	62	174.42	135.0	222.4	0.0555
Europe								
Tralokinumab Q2W + TCS	147	43.80	39 (26.5)	65	148.40	115.6	188.4	
Placebo + TCS	72	20.00	25 (34.7)	43	215.01	159.1	289.5	
Rest of World								
Tralokinumab Q2W + TCS	105	30.29	30 (28.6)	48	158.47	116.7	207.1	
Placebo + TCS	54	15.55	15 (27.8)	19	122.22	76.6	189.1	

The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. 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. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.6.279.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	126	126 7.9 (1.49)		252	251 7.7 (1.51)			
Week 16		112 4.7 (2.59)			226 3.5 (2.21)			
Week 16 chg		112 -3.1 (2.51)	-3.03 (0.21)		226 -4.1 (2.42)	-4.13 (0.15)	-1.10 (-1.61, -0.58) [-0.45 (-0.68, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0859
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.279.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Europe								
Baseline	72	72 7.6 (1.40)		147	146 7.6 (1.47)			
Week 16		63 4.3 (2.33)			137 3.6 (2.13)			
Week 16 chg		63 -3.2 (2.28)	-3.27 (0.27)		137 -4.0 (2.37)	-3.98 (0.18)	-0.71 (-1.36, -0.07) [-0.30 (-0.60, -0.00)]	0.031

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0859
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.279.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	54	54 8.2 (1.56)		105	105 7.7 (1.58)			
Week 16		49 5.2 (2.85)			89 3.3 (2.31)			
Week 16 chg		49 -3.0 (2.79)	-2.75 (0.35)		89 -4.2 (2.50)	-4.36 (0.26)	-1.61 (-2.47, -0.74) [-0.62 (-0.97, -0.26)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0859
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.280.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)			
Week 16		112 3.7 (2.86)			226 2.4 (2.25)			
Week 16 chg		112 -3.3 (2.59)	-3.23 (0.22)		226 -4.4 (2.62)	-4.42 (0.15)	-1.19 (-1.72, -0.67) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1303
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.280.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Europe								
Baseline	72	72 6.7 (2.15)		147	146 6.8 (2.07)			
Week 16		63 3.2 (2.51)			137 2.5 (2.19)			
Week 16 chg		63 -3.3 (2.31)	-3.44 (0.27)		137 -4.3 (2.51)	-4.29 (0.18)	-0.86 (-1.50, -0.21) [-0.35 (-0.65, -0.05)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1303
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.280.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World												
Baseline	54	54	7.6 (2.18)			105	105	7.0 (2.21)				
Week 16		49	4.4 (3.16)				89	2.4 (2.36)				
Week 16 chg		49	-3.2 (2.94)	-2.97	(0.36)		89	-4.5 (2.80)	-4.63	(0.27)	-1.66 (-2.56, -0.77) [-0.58 (-0.94, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1303
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.281.3.1: Total, Region, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
SCORAD Score								
Total								
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)			
Week 16		122 40.9 (23.52)			241 29.4 (18.62)			
Week 16 chg		122 -27.7 (22.50)	-26.93 (1.75)		241 -37.4 (19.31)	-37.74 (1.24)	-10.81 (-15.0, -6.58) [-0.53 (-0.75, -0.31)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0675
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.281.3.1: Total, Region, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Europe							
Baseline	72	72 69.8 (13.20)		147	147 68.2 (13.09)		
Week 16		69 39.3 (21.06)			143 31.3 (19.84)		
Week 16 chg		69 -30.4 (20.17)	-29.94 (2.28)		143 -36.9 (19.51)	-37.14 (1.58)	-7.20 (-12.7, -1.72) 0.010 [-0.37 (-0.65, -0.08)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0675
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.281.3.1: Total, Region, change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	54	54 67.5 (13.17)		105	105 65.2 (13.36)			
Week 16		53 43.0 (26.46)			98 26.7 (16.40)			
Week 16 chg		53 -24.2 (24.98)	-22.71 (2.65)		98 -38.1 (19.10)	-38.76 (1.94)	-16.05 (-22.6, -9.54) [-0.75 (-1.10, -0.41)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0675
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.282.3.1: Total, Region, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score								
Total								
Baseline	126	125 17.2 (7.15)		252	250 17.6 (7.07)			
Week 16		120 8.3 (7.27)			239 5.7 (6.00)			
Week 16 chg		119 -8.8 (7.09)	-8.95 (0.55)		237 -11.8 (7.57)	-11.74 (0.39)	-2.78 (-4.10, -1.47) [-0.38 (-0.60, -0.15)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3747
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.282.3.1: Total, Region, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Europe							
Baseline	72	72 16.6 (7.18)		147	146 18.3 (6.85)		
Week 16		68 7.6 (6.65)			142 5.9 (5.84)		
Week 16 chg		68 -9.0 (7.31)	-9.77 (0.71)		141 -12.3 (7.82)	-11.94 (0.49)	-2.17 (-3.88, -0.46) 0.013 [-0.28 (-0.57, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3747
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.282.3.1: Total, Region, change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	54	53 18.0 (7.10)		105	104 16.5 (7.27)			
Week 16		52 9.3 (7.98)			97 5.4 (6.25)			
Week 16 chg		51 -8.5 (6.86)	-8.02 (0.83)		96 -11.1 (7.17)	-11.35 (0.61)	-3.34 (-5.38, -1.29) [-0.47 (-0.82, -0.13)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3747
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.283.3.1: Total, Region, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	126	124 22.4 (5.63)		252	250 22.3 (5.09)			
Week 16		120 14.6 (8.22)			239 10.4 (7.20)			
Week 16 chg		118 -7.8 (7.40)	-7.74 (0.65)		237 -11.7 (7.37)	-11.74 (0.46)	-4.00 (-5.56, -2.44) [-0.54 (-0.77, -0.32)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4493
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.283.3.1: Total, Region, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Europe								
Baseline	72	71 22.0 (5.89)		147	146 23.0 (4.66)			
Week 16		68 14.3 (7.82)			142 11.2 (6.92)			
Week 16 chg		67 -8.0 (7.43)	-8.13 (0.84)		141 -11.7 (7.14)	-11.64 (0.58)	-3.51 (-5.51, -1.51) [-0.49 (-0.78, -0.19)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4493
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.283.3.1: Total, Region, change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	54	53 22.8 (5.27)		105	104 21.3 (5.52)			
Week 16		52 15.0 (8.78)			97 9.4 (7.49)			
Week 16 chg		51 -7.7 (7.43)	-7.20 (1.03)		96 -11.6 (7.74)	-11.88 (0.75)	-4.68 (-7.20, -2.15) [-0.61 (-0.96, -0.27)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4493
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.285.3.1: Total, Region, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	126	125	59.4 (23.09)		252	250	59.1 (25.01)		
Week 16		117	71.5 (21.13)			234	75.8 (18.76)		
Week 16 chg		116	12.4 (22.66)	12.50 (1.65)		232	17.0 (24.19)	16.95 (1.17)	4.45 (0.46, 8.43) 0.029 [0.19 (-0.04, 0.41)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1385
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.285.3.1: Total, Region, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Europe									
Baseline	72	72	52.8 (21.62)		147	146	50.0 (23.89)		
Week 16		66	71.1 (18.15)			140	72.3 (19.22)		
Week 16 chg		66	18.5 (21.63)	19.50 (2.22)		139	21.7 (26.46)	21.22 (1.53)	1.72 (-3.60, 7.05) 0.524 [0.07 (-0.22, 0.36)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1385
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.285.3.1: Total, Region, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World										
Baseline	54	53	68.4 (22.15)		105	104	71.9 (20.60)			
Week 16		51	71.9 (24.63)			94	81.0 (16.85)			
Week 16 chg		50	4.3 (21.61)	3.23 (2.40)		93	10.0 (18.36)	10.63 (1.76)	7.40 (1.50, 13.29) [0.38 (0.03, 0.72)]	0.014

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1385
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.286.3.1: Total, Region, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	126	126 6.9 (2.72)		252	252 6.5 (2.77)		
Week 16		122 3.2 (3.24)			241 2.2 (2.68)		
Week 16 chg		122 -3.7 (3.20)	-3.44 (0.25)		241 -4.2 (3.34)	-4.29 (0.18)	-0.85 (-1.45, -0.25) 0.006 [-0.26 (-0.48, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1699
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.286.3.1: Total, Region, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Europe							
Baseline	72	72 6.4 (2.82)		147	147 6.3 (2.76)		
Week 16		69 2.8 (2.94)			143 2.3 (2.79)		
Week 16 chg		69 -3.5 (3.04)	-3.47 (0.32)		143 -4.0 (3.19)	-3.96 (0.22)	-0.49 (-1.26, 0.27) 0.205 [-0.16 (-0.44, 0.13)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1699
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.286.3.1: Total, Region, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	54	54 7.6 (2.42)		105	105 6.6 (2.79)			
Week 16		53 3.7 (3.55)			98 2.0 (2.51)			
Week 16 chg		53 -3.9 (3.42)	-3.36 (0.40)		98 -4.5 (3.54)	-4.81 (0.29)	-1.45 (-2.43, -0.47) [-0.42 (-0.75, -0.08)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1699
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.291.3.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score											
Total											
Baseline	126	126	30.4 (12.78)			252	252	28.8 (11.97)			
Week 2		124	19.8 (12.98)				251	17.0 (11.25)			
Week 2 chg		124	-10.7 (11.46)	-10.25	(0.87)		251	-11.8 (10.37)	-12.03	(0.61)	-1.78 (-3.86, 0.30) 0.094 [-0.17 (-0.38, 0.05)]
Week 4		126	16.8 (13.62)				247	13.2 (10.47)			
Week 4 chg		126	-13.6 (12.25)	-13.09	(0.86)		247	-15.8 (11.28)	-15.88	(0.61)	-2.78 (-4.86, -0.70) 0.009 [-0.24 (-0.45, -0.02)]
Week 6		125	15.2 (13.41)				247	10.7 (9.46)			
Week 6 chg		125	-15.2 (12.09)	-14.70	(0.87)		247	-18.3 (11.21)	-18.31	(0.61)	-3.62 (-5.70, -1.53) <.001 [-0.31 (-0.53, -0.10)]
Week 8		122	13.6 (12.73)				243	9.3 (8.85)			
Week 8 chg		122	-16.7 (11.39)	-15.95	(0.87)		243	-19.8 (11.30)	-19.68	(0.61)	-3.73 (-5.82, -1.64) <.001 [-0.33 (-0.55, -0.11)]
Week 10		118	13.9 (13.56)				237	8.2 (8.42)			
Week 10 chg		118	-16.2 (11.61)	-15.71	(0.87)		237	-20.7 (12.01)	-20.64	(0.62)	-4.92 (-7.03, -2.82) <.001 [-0.41 (-0.64, -0.19)]
Week 12		119	12.9 (12.82)				238	8.0 (9.27)			
Week 12 chg		119	-17.2 (11.92)	-16.57	(0.87)		238	-21.1 (12.42)	-21.12	(0.62)	-4.55 (-6.65, -2.45) <.001 [-0.37 (-0.59, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1739
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 1.6.291.3.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	13.1 (13.79)		235	7.7 (9.25)			
Week 14 chg	118	-16.9 (13.53)	-16.27 (0.87)	235	-21.4 (12.29)	-21.30 (0.62)	-5.03 (-7.14, -2.93) [-0.40 (-0.62, -0.17)]	<.001
Week 16	123	14.1 (14.89)		241	8.1 (9.15)			
Week 16 chg	123	-16.0 (14.04)	-15.45 (0.87)	241	-20.7 (12.33)	-20.92 (0.62)	-5.47 (-7.56, -3.38) [-0.42 (-0.64, -0.20)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1739
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 1.6.291.3.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Europe							
Baseline	72	72 32.0 (13.61)		147	147 30.7 (12.07)		
Week 2		71 19.7 (13.23)			146 18.3 (11.66)		
Week 2 chg		71 -12.5 (12.13)	-12.14 (1.15)		146 -12.4 (10.24)	-12.58 (0.81)	-0.44 (-3.21, 2.32) 0.753 [-0.04 (-0.32, 0.24)]
Week 4		72 16.5 (13.77)			145 14.1 (11.59)		
Week 4 chg		72 -15.5 (12.29)	-15.15 (1.15)		145 -16.8 (11.34)	-16.86 (0.81)	-1.71 (-4.47, 1.05) 0.224 [-0.15 (-0.43, 0.14)]
Week 6		71 14.6 (12.55)			145 11.3 (10.19)		
Week 6 chg		71 -17.5 (12.19)	-17.04 (1.15)		145 -19.6 (11.26)	-19.70 (0.81)	-2.66 (-5.43, 0.11) 0.060 [-0.23 (-0.51, 0.06)]
Week 8		70 12.4 (11.84)			144 9.7 (9.26)		
Week 8 chg		70 -19.6 (11.24)	-19.11 (1.16)		144 -21.2 (10.91)	-21.16 (0.81)	-2.05 (-4.83, 0.72) 0.147 [-0.19 (-0.47, 0.10)]
Week 10		66 12.9 (12.94)			140 8.4 (8.85)		
Week 10 chg		66 -18.8 (11.48)	-18.61 (1.17)		140 -22.2 (11.51)	-22.21 (0.81)	-3.61 (-6.41, -0.81) 0.012 [-0.31 (-0.61, -0.02)]
Week 12		67 13.1 (12.70)			142 8.6 (10.42)		
Week 12 chg		67 -18.6 (12.02)	-18.34 (1.17)		142 -22.3 (12.83)	-22.34 (0.81)	-4.01 (-6.80, -1.21) 0.005 [-0.32 (-0.61, -0.03)]
Week 14		67 12.1 (13.02)			138 8.5 (10.32)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1739
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 1.6.291.3.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	67	-19.2 (13.07)	-18.90 (1.17)	138	-22.4 (13.12)	-22.31 (0.81)	-3.41 (-6.21, -0.61) [-0.26 (-0.55, 0.03)]	0.017
Week 16	70	13.1 (14.38)		143	9.0 (10.14)			
Week 16 chg	70	-18.6 (13.74)	-18.27 (1.16)	143	-21.6 (12.98)	-21.89 (0.81)	-3.61 (-6.39, -0.84) [-0.27 (-0.56, 0.01)]	0.011

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1739
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 1.6.291.3.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	54	54 28.3 (11.36)		105	105 26.2 (11.37)		
Week 2		53 20.0 (12.75)			105 15.3 (10.46)		
Week 2 chg		53 -8.4 (10.12)	-7.58 (1.30)		105 -11.0 (10.54)	-11.30 (0.93)	-3.72 (-6.87, -0.57) 0.021 [-0.36 (-0.69, -0.02)]
Week 4		54 17.3 (13.54)			102 12.0 (8.56)		
Week 4 chg		54 -11.0 (11.81)	-10.16 (1.30)		102 -14.5 (11.12)	-14.55 (0.93)	-4.39 (-7.55, -1.24) 0.007 [-0.39 (-0.72, -0.05)]
Week 6		54 16.0 (14.54)			102 9.9 (8.30)		
Week 6 chg		54 -12.2 (11.37)	-11.45 (1.30)		102 -16.4 (10.93)	-16.39 (0.93)	-4.95 (-8.10, -1.79) 0.002 [-0.45 (-0.78, -0.11)]
Week 8		52 15.4 (13.76)			99 8.6 (8.23)		
Week 8 chg		52 -12.7 (10.45)	-11.59 (1.30)		99 -17.7 (11.59)	-17.62 (0.94)	-6.03 (-9.20, -2.86) <.001 [-0.54 (-0.88, -0.20)]
Week 10		52 15.2 (14.34)			97 7.8 (7.78)		
Week 10 chg		52 -12.9 (11.01)	-11.71 (1.30)		97 -18.4 (12.40)	-18.44 (0.94)	-6.73 (-9.90, -3.55) <.001 [-0.56 (-0.91, -0.22)]
Week 12		52 12.7 (13.09)			96 7.0 (7.16)		
Week 12 chg		52 -15.2 (11.61)	-13.99 (1.30)		96 -19.4 (11.64)	-19.46 (0.94)	-5.46 (-8.63, -2.29) <.001 [-0.47 (-0.81, -0.13)]
Week 14		51 14.4 (14.76)			97 6.4 (7.36)		

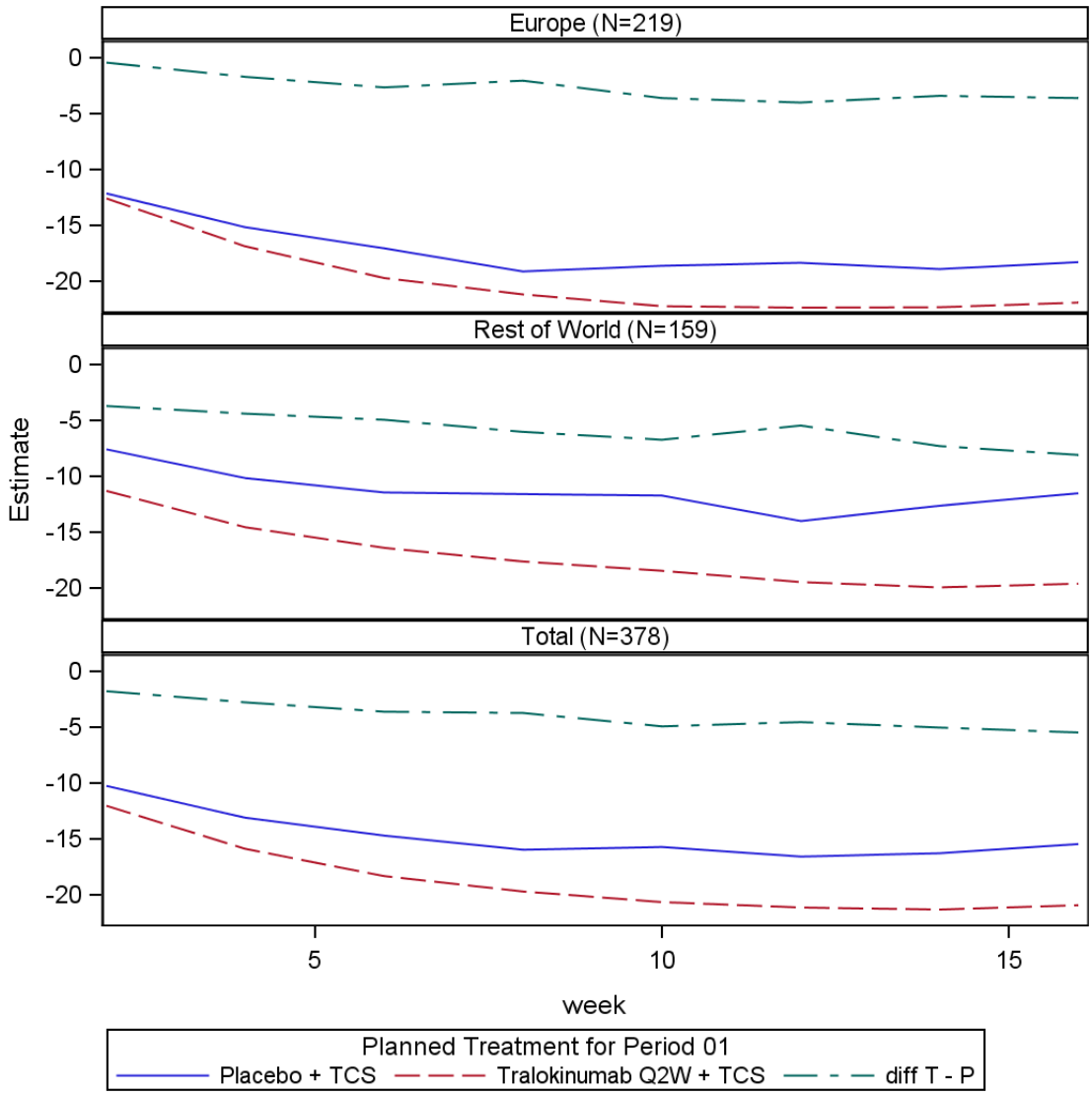
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1739
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.6.291.3.1: Total, Region, change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	51	-13.9 (13.66)	-12.63 (1.31)	97	-19.9 (10.89)	-19.93 (0.94)	-7.30 (-10.5, -4.12) [-0.61 (-0.96, -0.27)]	<.001
Week 16	53	15.3 (15.59)		98	6.6 (7.27)			
Week 16 chg	53	-12.5 (13.80)	-11.51 (1.30)	98	-19.2 (11.23)	-19.60 (0.94)	-8.09 (-11.3, -4.92) [-0.66 (-1.01, -0.32)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1739
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 1.6.291.3.2: Total, Region, change in EASI, Treatment policy estimand, LP0162-1339, 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 1.6.293.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)										
Total										
Baseline	126	126	7.9 (1.49)		252	251	7.7 (1.51)			
Week 1		125	6.5 (1.78)			248	6.2 (1.90)			
Week 1 chg		125	-1.3 (1.50)	-1.27 (0.19)		248	-1.5 (1.56)	-1.50 (0.14)	-0.23 (-0.69, 0.24) [-0.15 (-0.36, 0.07)]	0.336
Week 2		126	6.0 (2.11)			245	5.5 (2.23)			
Week 2 chg		126	-1.8 (2.00)	-1.80 (0.19)		245	-2.2 (2.02)	-2.19 (0.14)	-0.39 (-0.85, 0.07) [-0.19 (-0.41, 0.02)]	0.097
Week 3		125	5.8 (2.18)			243	5.0 (2.26)			
Week 3 chg		125	-2.0 (2.05)	-1.97 (0.19)		243	-2.6 (2.15)	-2.65 (0.14)	-0.68 (-1.15, -0.22) [-0.32 (-0.54, -0.11)]	0.004
Week 4		120	5.5 (2.39)			244	4.8 (2.29)			
Week 4 chg		120	-2.4 (2.21)	-2.31 (0.19)		244	-2.9 (2.21)	-2.92 (0.14)	-0.62 (-1.08, -0.15) [-0.28 (-0.50, -0.06)]	0.009
Week 5		118	5.2 (2.42)			238	4.5 (2.21)			
Week 5 chg		118	-2.7 (2.31)	-2.62 (0.19)		238	-3.2 (2.19)	-3.19 (0.14)	-0.56 (-1.03, -0.10) [-0.25 (-0.47, -0.03)]	0.018
Week 6		122	5.1 (2.50)			239	4.3 (2.23)			
Week 6 chg		122	-2.7 (2.39)	-2.68 (0.19)		239	-3.3 (2.26)	-3.30 (0.14)	-0.62 (-1.08, -0.15) [-0.27 (-0.49, -0.05)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5577
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 1.6.293.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	116	4.9 (2.48)		231	4.2 (2.27)			
Week 7 chg	116	-2.9 (2.41)	-2.79 (0.19)	231	-3.5 (2.29)	-3.47 (0.14)	-0.68 (-1.15, -0.22) [-0.29 (-0.52, -0.07)]	0.004
Week 8	116	4.9 (2.49)		227	4.0 (2.31)			
Week 8 chg	116	-2.9 (2.38)	-2.81 (0.19)	227	-3.6 (2.35)	-3.60 (0.14)	-0.79 (-1.26, -0.32) [-0.34 (-0.56, -0.11)]	<.001
Week 9	116	4.9 (2.53)		235	3.9 (2.24)			
Week 9 chg	116	-3.0 (2.35)	-2.88 (0.19)	235	-3.7 (2.31)	-3.75 (0.14)	-0.87 (-1.33, -0.40) [-0.37 (-0.60, -0.15)]	<.001
Week 10	114	4.8 (2.56)		235	3.8 (2.27)			
Week 10 chg	114	-3.0 (2.45)	-2.97 (0.19)	235	-3.8 (2.43)	-3.82 (0.14)	-0.85 (-1.31, -0.38) [-0.35 (-0.57, -0.12)]	<.001
Week 11	115	4.8 (2.54)		231	3.6 (2.19)			
Week 11 chg	115	-3.0 (2.48)	-2.96 (0.19)	231	-4.0 (2.39)	-4.03 (0.14)	-1.06 (-1.53, -0.60) [-0.44 (-0.67, -0.21)]	<.001
Week 12	115	4.7 (2.55)		234	3.7 (2.15)			
Week 12 chg	115	-3.1 (2.41)	-2.99 (0.19)	234	-3.9 (2.40)	-3.97 (0.14)	-0.98 (-1.45, -0.51) [-0.41 (-0.63, -0.18)]	<.001
Week 13	115	4.8 (2.53)		233	3.6 (2.19)			
Week 13 chg	115	-3.1 (2.37)	-3.00 (0.19)	233	-4.1 (2.44)	-4.12 (0.14)	-1.12 (-1.59, -0.65) [-0.46 (-0.69, -0.24)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5577
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 1.6.293.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	116	4.7 (2.57)		223	3.6 (2.20)		
Week 14 chg	116	-3.1 (2.42)	-3.00 (0.19)	223	-4.0 (2.49)	-4.05 (0.14)	-1.05 (-1.52, -0.58) <.001 [-0.43 (-0.65, -0.20)]
Week 15	114	4.8 (2.59)		225	3.5 (2.20)		
Week 15 chg	114	-3.0 (2.44)	-3.00 (0.19)	225	-4.1 (2.43)	-4.10 (0.14)	-1.10 (-1.57, -0.63) <.001 [-0.45 (-0.68, -0.22)]
Week 16	112	4.7 (2.59)		226	3.5 (2.21)		
Week 16 chg	112	-3.1 (2.51)	-2.99 (0.19)	226	-4.1 (2.42)	-4.12 (0.14)	-1.13 (-1.60, -0.66) <.001 [-0.46 (-0.69, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5577
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 1.6.293.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Europe								
Baseline	72	72 7.6 (1.40)		147	146 7.6 (1.47)			
Week 1		71 6.2 (1.67)			145 6.1 (1.87)			
Week 1 chg		71 -1.4 (1.48)	-1.37 (0.24)		145 -1.5 (1.41)	-1.51 (0.17)	-0.14 (-0.72, 0.44) [-0.10 (-0.38, 0.19)]	0.640
Week 2		72 5.5 (2.04)			143 5.5 (2.12)			
Week 2 chg		72 -2.1 (2.09)	-2.11 (0.24)		143 -2.2 (1.77)	-2.16 (0.17)	-0.05 (-0.63, 0.53) [-0.03 (-0.31, 0.26)]	0.863
Week 3		71 5.4 (2.08)			143 5.0 (2.14)			
Week 3 chg		71 -2.2 (2.10)	-2.24 (0.24)		143 -2.7 (1.85)	-2.67 (0.17)	-0.43 (-1.01, 0.15) [-0.22 (-0.51, 0.06)]	0.148
Week 4		70 5.1 (2.27)			142 4.7 (2.26)			
Week 4 chg		70 -2.5 (2.22)	-2.60 (0.24)		142 -3.0 (2.02)	-2.99 (0.17)	-0.40 (-0.98, 0.18) [-0.19 (-0.48, 0.10)]	0.180
Week 5		68 4.8 (2.36)			141 4.4 (2.14)			
Week 5 chg		68 -2.8 (2.32)	-2.84 (0.24)		141 -3.3 (2.05)	-3.24 (0.17)	-0.40 (-0.98, 0.18) [-0.19 (-0.48, 0.10)]	0.180
Week 6		70 4.8 (2.35)			141 4.3 (2.17)			
Week 6 chg		70 -2.9 (2.32)	-2.92 (0.24)		141 -3.4 (2.14)	-3.32 (0.17)	-0.40 (-0.98, 0.18) [-0.18 (-0.47, 0.11)]	0.178
Week 7		68 4.6 (2.30)			138 4.1 (2.20)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5577
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 1.6.293.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	68	68	-3.0 (2.28)	-3.01	(0.24)	138	138	-3.6 (2.21)	-3.54	(0.17)	-0.53 (-1.11, 0.05) [-0.24 (-0.53, 0.05)]	0.074
Week 8	65	65	4.5 (2.28)			136	136	4.0 (2.25)				
Week 8 chg	65	65	-3.1 (2.27)	-3.09	(0.24)	136	136	-3.6 (2.21)	-3.60	(0.17)	-0.51 (-1.10, 0.07) [-0.23 (-0.53, 0.07)]	0.085
Week 9	67	67	4.5 (2.37)			141	141	3.9 (2.21)				
Week 9 chg	67	67	-3.1 (2.28)	-3.18	(0.24)	141	141	-3.7 (2.16)	-3.70	(0.17)	-0.51 (-1.10, 0.07) [-0.23 (-0.53, 0.06)]	0.083
Week 10	66	66	4.4 (2.37)			140	140	3.8 (2.16)				
Week 10 chg	66	66	-3.2 (2.34)	-3.28	(0.24)	140	140	-3.8 (2.28)	-3.79	(0.17)	-0.51 (-1.09, 0.08) [-0.22 (-0.51, 0.07)]	0.089
Week 11	66	66	4.4 (2.46)			137	137	3.6 (2.09)				
Week 11 chg	66	66	-3.2 (2.43)	-3.23	(0.24)	137	137	-4.0 (2.21)	-3.98	(0.17)	-0.75 (-1.33, -0.16) [-0.33 (-0.62, -0.03)]	0.012
Week 12	67	67	4.3 (2.43)			140	140	3.7 (2.07)				
Week 12 chg	67	67	-3.3 (2.28)	-3.31	(0.24)	140	140	-3.9 (2.22)	-3.89	(0.17)	-0.58 (-1.17, 0.00) [-0.26 (-0.55, 0.03)]	0.050
Week 13	67	67	4.4 (2.40)			139	139	3.5 (2.14)				
Week 13 chg	67	67	-3.2 (2.26)	-3.31	(0.24)	139	139	-4.1 (2.30)	-4.05	(0.17)	-0.75 (-1.33, -0.16) [-0.33 (-0.62, -0.03)]	0.012
Week 14	67	67	4.4 (2.45)			136	136	3.5 (2.10)				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5577
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 1.6.293.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	67	-3.2 (2.27)	-3.26 (0.24)	136	-4.1 (2.34)	-4.02 (0.17)	-0.76 (-1.34, -0.17) [-0.33 (-0.62, -0.03)]	0.011
Week 15	67	4.4 (2.45)		135	3.6 (2.17)			
Week 15 chg	67	-3.2 (2.28)	-3.23 (0.24)	135	-4.1 (2.37)	-4.01 (0.17)	-0.77 (-1.36, -0.19) [-0.33 (-0.63, -0.04)]	0.010
Week 16	63	4.3 (2.33)		137	3.6 (2.13)			
Week 16 chg	63	-3.2 (2.28)	-3.18 (0.25)	137	-4.0 (2.37)	-3.95 (0.17)	-0.78 (-1.36, -0.19) [-0.33 (-0.63, -0.03)]	0.010

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5577
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 1.6.293.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	54	54 8.2 (1.56)		105	105 7.7 (1.58)			
Week 1		54 6.9 (1.85)			103 6.2 (1.96)			
Week 1 chg		54 -1.2 (1.54)	-1.10 (0.31)		103 -1.5 (1.75)	-1.50 (0.22)	-0.40 (-1.16, 0.35) [-0.24 (-0.57, 0.09)]	0.294
Week 2		54 6.7 (2.04)			102 5.5 (2.39)			
Week 2 chg		54 -1.5 (1.82)	-1.34 (0.31)		102 -2.2 (2.33)	-2.24 (0.22)	-0.91 (-1.66, -0.15) [-0.42 (-0.75, -0.08)]	0.019
Week 3		54 6.4 (2.19)			100 5.1 (2.41)			
Week 3 chg		54 -1.7 (1.97)	-1.56 (0.31)		100 -2.6 (2.52)	-2.66 (0.22)	-1.10 (-1.85, -0.34) [-0.47 (-0.80, -0.13)]	0.005
Week 4		50 6.1 (2.45)			102 4.9 (2.34)			
Week 4 chg		50 -2.1 (2.19)	-1.87 (0.31)		102 -2.8 (2.46)	-2.85 (0.22)	-0.98 (-1.74, -0.22) [-0.41 (-0.75, -0.07)]	0.012
Week 5		50 5.6 (2.44)			97 4.6 (2.31)			
Week 5 chg		50 -2.5 (2.30)	-2.30 (0.31)		97 -3.1 (2.39)	-3.12 (0.22)	-0.82 (-1.58, -0.06) [-0.35 (-0.69, -0.00)]	0.036
Week 6		52 5.6 (2.62)			98 4.4 (2.32)			
Week 6 chg		52 -2.5 (2.49)	-2.33 (0.31)		98 -3.3 (2.42)	-3.27 (0.22)	-0.94 (-1.70, -0.18) [-0.38 (-0.72, -0.05)]	0.015
Week 7		48 5.4 (2.67)			93 4.3 (2.37)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5577
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 1.6.293.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	48	-2.7 (2.59)	-2.48 (0.31)	93	-3.3 (2.40)	-3.37 (0.23)	-0.89 (-1.65, -0.12) [-0.36 (-0.71, -0.01)]	0.024
Week 8	51	5.5 (2.66)		91	4.1 (2.41)			
Week 8 chg	51	-2.7 (2.51)	-2.41 (0.31)	91	-3.5 (2.54)	-3.62 (0.23)	-1.21 (-1.97, -0.44) [-0.48 (-0.82, -0.13)]	0.002
Week 9	49	5.4 (2.65)		94	3.9 (2.29)			
Week 9 chg	49	-2.7 (2.44)	-2.45 (0.31)	94	-3.8 (2.53)	-3.85 (0.22)	-1.41 (-2.17, -0.64) [-0.56 (-0.92, -0.21)]	<.001
Week 10	48	5.4 (2.71)		95	3.9 (2.44)			
Week 10 chg	48	-2.7 (2.60)	-2.54 (0.32)	95	-3.8 (2.66)	-3.87 (0.22)	-1.33 (-2.10, -0.57) [-0.50 (-0.86, -0.15)]	<.001
Week 11	49	5.2 (2.60)		94	3.6 (2.34)			
Week 11 chg	49	-2.9 (2.58)	-2.57 (0.31)	94	-4.0 (2.65)	-4.12 (0.23)	-1.54 (-2.31, -0.78) [-0.59 (-0.94, -0.24)]	<.001
Week 12	48	5.3 (2.65)		94	3.7 (2.27)			
Week 12 chg	48	-2.9 (2.58)	-2.52 (0.32)	94	-3.9 (2.67)	-4.12 (0.23)	-1.60 (-2.37, -0.84) [-0.61 (-0.96, -0.25)]	<.001
Week 13	48	5.3 (2.64)		94	3.6 (2.28)			
Week 13 chg	48	-2.9 (2.52)	-2.55 (0.32)	94	-4.1 (2.64)	-4.24 (0.22)	-1.69 (-2.46, -0.92) [-0.65 (-1.00, -0.29)]	<.001
Week 14	49	5.2 (2.69)		87	3.7 (2.35)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5577
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.

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Table 1.6.293.3.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	49	-3.0 (2.63)	-2.62 (0.31)	87	-3.9 (2.71)	-4.12 (0.23)	-1.50 (-2.27, -0.73) [-0.56 (-0.92, -0.20)]	<.001
Week 15	47	5.3 (2.70)		90	3.5 (2.26)			
Week 15 chg	47	-2.8 (2.66)	-2.65 (0.32)	90	-4.1 (2.53)	-4.25 (0.23)	-1.59 (-2.36, -0.83) [-0.62 (-0.98, -0.26)]	<.001
Week 16	49	5.2 (2.85)		89	3.3 (2.31)			
Week 16 chg	49	-3.0 (2.79)	-2.73 (0.31)	89	-4.2 (2.50)	-4.38 (0.23)	-1.65 (-2.41, -0.88) [-0.63 (-0.99, -0.28)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5577
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.

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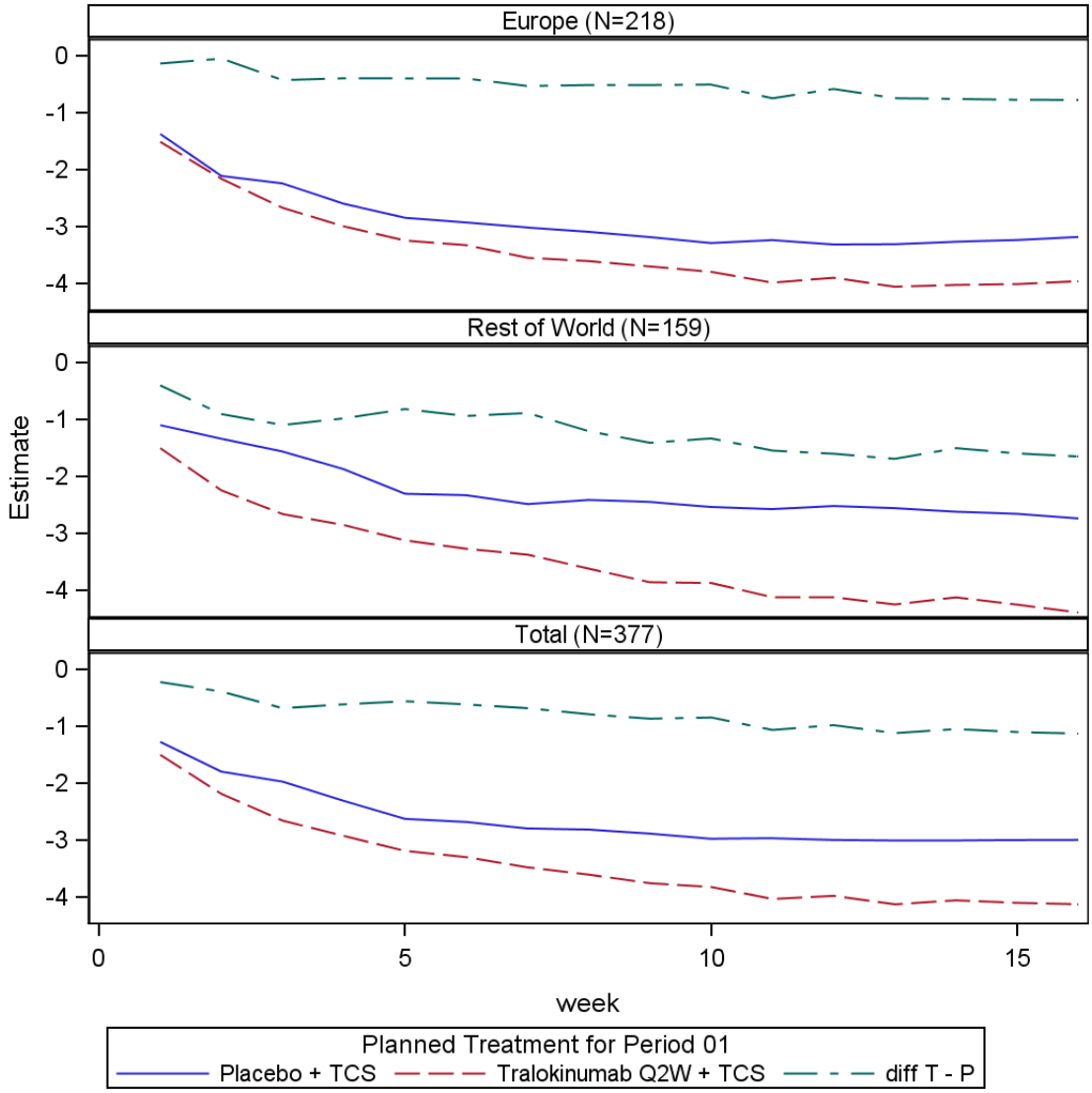
Figure 1.6.293.3.2: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16



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 1.6.295.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)		
Week 1		125 5.7 (2.39)			248 5.3 (2.33)		
Week 1 chg		125 -1.4 (1.62)	-1.38 (0.20)		248 -1.6 (1.68)	-1.56 (0.14)	-0.18 (-0.65, 0.30) 0.468 [-0.11 (-0.32, 0.11)]
Week 2		126 5.1 (2.66)			245 4.5 (2.54)		
Week 2 chg		126 -1.9 (2.16)	-1.90 (0.20)		245 -2.4 (2.19)	-2.35 (0.14)	-0.45 (-0.93, 0.03) 0.066 [-0.21 (-0.42, 0.01)]
Week 3		125 4.9 (2.61)			243 4.0 (2.57)		
Week 3 chg		125 -2.2 (2.17)	-2.11 (0.20)		243 -2.9 (2.33)	-2.90 (0.14)	-0.79 (-1.27, -0.31) 0.001 [-0.35 (-0.56, -0.13)]
Week 4		120 4.6 (2.69)			244 3.8 (2.59)		
Week 4 chg		120 -2.5 (2.26)	-2.44 (0.20)		244 -3.1 (2.41)	-3.15 (0.14)	-0.70 (-1.18, -0.22) 0.004 [-0.30 (-0.52, -0.08)]
Week 5		118 4.3 (2.71)			238 3.4 (2.50)		
Week 5 chg		118 -2.8 (2.32)	-2.70 (0.20)		238 -3.5 (2.40)	-3.48 (0.14)	-0.78 (-1.26, -0.30) 0.002 [-0.33 (-0.55, -0.11)]
Week 6		122 4.3 (2.76)			239 3.2 (2.50)		
Week 6 chg		122 -2.7 (2.43)	-2.70 (0.20)		239 -3.6 (2.53)	-3.61 (0.14)	-0.91 (-1.39, -0.43) <.001 [-0.36 (-0.58, -0.14)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5006
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 1.6.295.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	116	4.0 (2.76)		231	3.0 (2.47)		
Week 7 chg	116	-3.0 (2.49)	-2.97 (0.20)	231	-3.8 (2.52)	-3.81 (0.14)	-0.84 (-1.32, -0.36) <.001 [-0.34 (-0.56, -0.11)]
Week 8	116	4.0 (2.72)		227	3.0 (2.49)		
Week 8 chg	116	-3.0 (2.48)	-2.92 (0.20)	227	-3.9 (2.52)	-3.87 (0.14)	-0.95 (-1.43, -0.47) <.001 [-0.38 (-0.60, -0.15)]
Week 9	116	3.9 (2.78)		235	2.8 (2.36)		
Week 9 chg	116	-3.1 (2.48)	-3.03 (0.20)	235	-4.1 (2.49)	-4.07 (0.14)	-1.04 (-1.52, -0.56) <.001 [-0.42 (-0.64, -0.19)]
Week 10	114	3.9 (2.81)		235	2.7 (2.40)		
Week 10 chg	114	-3.1 (2.56)	-3.09 (0.20)	235	-4.1 (2.59)	-4.11 (0.14)	-1.02 (-1.50, -0.54) <.001 [-0.40 (-0.62, -0.17)]
Week 11	115	3.8 (2.71)		231	2.6 (2.33)		
Week 11 chg	115	-3.2 (2.54)	-3.10 (0.20)	231	-4.2 (2.58)	-4.22 (0.14)	-1.12 (-1.60, -0.64) <.001 [-0.44 (-0.66, -0.21)]
Week 12	115	3.8 (2.78)		234	2.7 (2.32)		
Week 12 chg	115	-3.2 (2.59)	-3.10 (0.20)	234	-4.2 (2.61)	-4.19 (0.14)	-1.09 (-1.57, -0.61) <.001 [-0.42 (-0.64, -0.19)]
Week 13	115	3.9 (2.80)		233	2.5 (2.33)		
Week 13 chg	115	-3.2 (2.52)	-3.16 (0.20)	233	-4.4 (2.66)	-4.39 (0.14)	-1.24 (-1.72, -0.75) <.001 [-0.47 (-0.70, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5006
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 1.6.295.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	116	3.8 (2.86)		223	2.5 (2.29)			
Week 14 chg	116	-3.2 (2.61)	-3.14 (0.20)	223	-4.3 (2.69)	-4.33 (0.14)	-1.20 (-1.68, -0.72) [-0.45 (-0.68, -0.22)]	<.001
Week 15	114	3.8 (2.87)		225	2.4 (2.27)			
Week 15 chg	114	-3.2 (2.56)	-3.14 (0.20)	225	-4.4 (2.64)	-4.39 (0.14)	-1.25 (-1.73, -0.77) [-0.48 (-0.71, -0.25)]	<.001
Week 16	112	3.7 (2.86)		226	2.4 (2.25)			
Week 16 chg	112	-3.3 (2.59)	-3.19 (0.20)	226	-4.4 (2.62)	-4.39 (0.14)	-1.21 (-1.69, -0.72) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5006
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 1.6.295.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Europe								
Baseline	72	72 6.7 (2.15)		147	146 6.8 (2.07)			
Week 1		71 5.2 (2.18)			145 5.3 (2.30)			
Week 1 chg		71 -1.5 (1.50)	-1.44 (0.24)		145 -1.5 (1.56)	-1.53 (0.17)	-0.10 (-0.69, 0.49) [-0.06 (-0.35, 0.22)]	0.747
Week 2		72 4.5 (2.47)			143 4.5 (2.39)			
Week 2 chg		72 -2.2 (2.14)	-2.19 (0.24)		143 -2.4 (1.99)	-2.32 (0.17)	-0.13 (-0.72, 0.45) [-0.07 (-0.35, 0.22)]	0.655
Week 3		71 4.4 (2.36)			143 3.8 (2.39)			
Week 3 chg		71 -2.3 (2.13)	-2.36 (0.24)		143 -3.0 (2.05)	-2.96 (0.17)	-0.60 (-1.19, -0.01) [-0.29 (-0.57, -0.00)]	0.046
Week 4		70 4.1 (2.45)			142 3.6 (2.45)			
Week 4 chg		70 -2.6 (2.21)	-2.70 (0.25)		142 -3.2 (2.16)	-3.21 (0.17)	-0.51 (-1.10, 0.08) [-0.23 (-0.52, 0.05)]	0.092
Week 5		68 3.8 (2.49)			141 3.2 (2.37)			
Week 5 chg		68 -2.9 (2.25)	-2.93 (0.25)		141 -3.6 (2.23)	-3.56 (0.17)	-0.63 (-1.22, -0.04) [-0.28 (-0.57, 0.01)]	0.037
Week 6		70 3.8 (2.49)			141 3.1 (2.34)			
Week 6 chg		70 -2.9 (2.36)	-2.97 (0.25)		141 -3.7 (2.38)	-3.65 (0.17)	-0.69 (-1.28, -0.10) [-0.29 (-0.58, -0.00)]	0.023
Week 7		68 3.5 (2.48)			138 2.9 (2.32)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5006
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 1.6.295.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg		68	-3.2 (2.33)	-3.19 (0.25)		138	-4.0 (2.37)	-3.92 (0.17)			-0.73 (-1.32, -0.14) [-0.31 (-0.60, -0.02)]	0.016
Week 8		65	3.5 (2.32)			136	2.9 (2.39)					
Week 8 chg		65	-3.2 (2.26)	-3.16 (0.25)		136	-3.9 (2.37)	-3.86 (0.17)			-0.70 (-1.29, -0.11) [-0.30 (-0.60, -0.00)]	0.021
Week 9		67	3.4 (2.46)			141	2.7 (2.36)					
Week 9 chg		67	-3.2 (2.30)	-3.29 (0.25)		141	-4.1 (2.32)	-4.05 (0.17)			-0.76 (-1.35, -0.16) [-0.33 (-0.62, -0.03)]	0.013
Week 10		66	3.4 (2.52)			140	2.7 (2.33)					
Week 10 chg		66	-3.2 (2.36)	-3.34 (0.25)		140	-4.2 (2.45)	-4.08 (0.17)			-0.74 (-1.34, -0.15) [-0.31 (-0.60, -0.01)]	0.014
Week 11		66	3.4 (2.54)			137	2.5 (2.28)					
Week 11 chg		66	-3.2 (2.40)	-3.31 (0.25)		137	-4.3 (2.44)	-4.21 (0.17)			-0.90 (-1.49, -0.30) [-0.37 (-0.67, -0.07)]	0.003
Week 12		67	3.5 (2.55)			140	2.6 (2.33)					
Week 12 chg		67	-3.2 (2.33)	-3.28 (0.25)		140	-4.2 (2.46)	-4.13 (0.17)			-0.85 (-1.45, -0.26) [-0.35 (-0.65, -0.06)]	0.005
Week 13		67	3.4 (2.53)			139	2.4 (2.28)					
Week 13 chg		67	-3.2 (2.24)	-3.38 (0.25)		139	-4.4 (2.43)	-4.33 (0.17)			-0.95 (-1.54, -0.35) [-0.40 (-0.69, -0.11)]	0.002
Week 14		67	3.4 (2.66)			136	2.4 (2.21)					

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5006
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
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Table 1.6.295.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	67	-3.2 (2.36)	-3.34 (0.25)	136	-4.4 (2.54)	-4.28 (0.17)	-0.95 (-1.54, -0.35) [-0.38 (-0.67, -0.09)]	0.002
Week 15	67	3.4 (2.60)		135	2.4 (2.24)			
Week 15 chg	67	-3.2 (2.30)	-3.36 (0.25)	135	-4.4 (2.53)	-4.29 (0.17)	-0.92 (-1.52, -0.33) [-0.37 (-0.67, -0.08)]	0.002
Week 16	63	3.2 (2.51)		137	2.5 (2.19)			
Week 16 chg	63	-3.3 (2.31)	-3.35 (0.25)	137	-4.3 (2.51)	-4.25 (0.17)	-0.90 (-1.50, -0.30) [-0.37 (-0.67, -0.07)]	0.003

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Test for treatment and subgroup interaction: 0.5006
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 1.6.295.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	54	54 7.6 (2.18)		105	105 7.0 (2.21)			
Week 1		54 6.2 (2.56)			103 5.4 (2.38)			
Week 1 chg		54 -1.4 (1.77)	-1.28 (0.33)		103 -1.6 (1.86)	-1.61 (0.24)	-0.33 (-1.13, 0.47) [-0.18 (-0.51, 0.15)]	0.422
Week 2		54 6.0 (2.69)			102 4.6 (2.76)			
Week 2 chg		54 -1.6 (2.17)	-1.50 (0.33)		102 -2.4 (2.46)	-2.40 (0.24)	-0.90 (-1.70, -0.09) [-0.38 (-0.71, -0.05)]	0.029
Week 3		54 5.7 (2.75)			100 4.2 (2.79)			
Week 3 chg		54 -1.9 (2.22)	-1.77 (0.33)		100 -2.8 (2.70)	-2.84 (0.24)	-1.07 (-1.87, -0.27) [-0.42 (-0.76, -0.09)]	0.009
Week 4		50 5.3 (2.87)			102 4.0 (2.77)			
Week 4 chg		50 -2.3 (2.32)	-2.06 (0.33)		102 -3.0 (2.73)	-3.07 (0.24)	-1.00 (-1.81, -0.20) [-0.39 (-0.73, -0.04)]	0.015
Week 5		50 4.9 (2.89)			97 3.6 (2.68)			
Week 5 chg		50 -2.6 (2.43)	-2.39 (0.33)		97 -3.3 (2.62)	-3.37 (0.24)	-0.99 (-1.79, -0.18) [-0.38 (-0.73, -0.04)]	0.017
Week 6		52 5.0 (2.96)			98 3.4 (2.71)			
Week 6 chg		52 -2.5 (2.52)	-2.35 (0.33)		98 -3.5 (2.75)	-3.54 (0.24)	-1.19 (-2.00, -0.39) [-0.45 (-0.79, -0.11)]	0.004
Week 7		48 4.6 (3.02)			93 3.3 (2.67)			

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Test for treatment and subgroup interaction: 0.5006
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
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Table 1.6.295.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	48	-2.9 (2.73)	-2.66 (0.33)	93	-3.6 (2.71)	-3.65 (0.24)	-0.98 (-1.80, -0.17) [-0.36 (-0.71, -0.01)]	0.018
Week 8	51	4.7 (3.04)		91	3.1 (2.65)			
Week 8 chg	51	-2.9 (2.75)	-2.58 (0.33)	91	-3.8 (2.73)	-3.89 (0.24)	-1.31 (-2.12, -0.50) [-0.48 (-0.83, -0.13)]	0.002
Week 9	49	4.6 (3.07)		94	2.9 (2.37)			
Week 9 chg	49	-3.0 (2.72)	-2.63 (0.33)	94	-4.0 (2.73)	-4.12 (0.24)	-1.49 (-2.30, -0.68) [-0.55 (-0.90, -0.19)]	<.001
Week 10	48	4.6 (3.07)		95	2.8 (2.50)			
Week 10 chg	48	-2.9 (2.82)	-2.74 (0.33)	95	-4.0 (2.80)	-4.17 (0.24)	-1.44 (-2.25, -0.63) [-0.51 (-0.86, -0.16)]	<.001
Week 11	49	4.3 (2.86)		94	2.8 (2.39)			
Week 11 chg	49	-3.2 (2.75)	-2.79 (0.33)	94	-4.1 (2.78)	-4.26 (0.24)	-1.48 (-2.29, -0.67) [-0.53 (-0.88, -0.18)]	<.001
Week 12	48	4.3 (3.03)		94	2.8 (2.32)			
Week 12 chg	48	-3.2 (2.94)	-2.82 (0.33)	94	-4.1 (2.83)	-4.32 (0.24)	-1.50 (-2.31, -0.69) [-0.52 (-0.88, -0.17)]	<.001
Week 13	48	4.6 (3.05)		94	2.6 (2.41)			
Week 13 chg	48	-3.1 (2.88)	-2.78 (0.33)	94	-4.3 (2.97)	-4.52 (0.24)	-1.74 (-2.55, -0.92) [-0.59 (-0.94, -0.24)]	<.001
Week 14	49	4.3 (3.07)		87	2.7 (2.41)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5006
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Table 1.6.295.3.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	49	-3.3 (2.94)	-2.83 (0.33)	87	-4.2 (2.91)	-4.44 (0.24)	-1.62 (-2.43, -0.80) [-0.55 (-0.91, -0.20)]	<.001
Week 15	47	4.5 (3.12)		90	2.5 (2.32)			
Week 15 chg	47	-3.0 (2.91)	-2.79 (0.34)	90	-4.5 (2.80)	-4.56 (0.24)	-1.77 (-2.58, -0.95) [-0.62 (-0.98, -0.26)]	<.001
Week 16	49	4.4 (3.16)		89	2.4 (2.36)			
Week 16 chg	49	-3.2 (2.94)	-2.94 (0.33)	89	-4.5 (2.80)	-4.64 (0.24)	-1.70 (-2.51, -0.89) [-0.60 (-0.95, -0.24)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5006
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.

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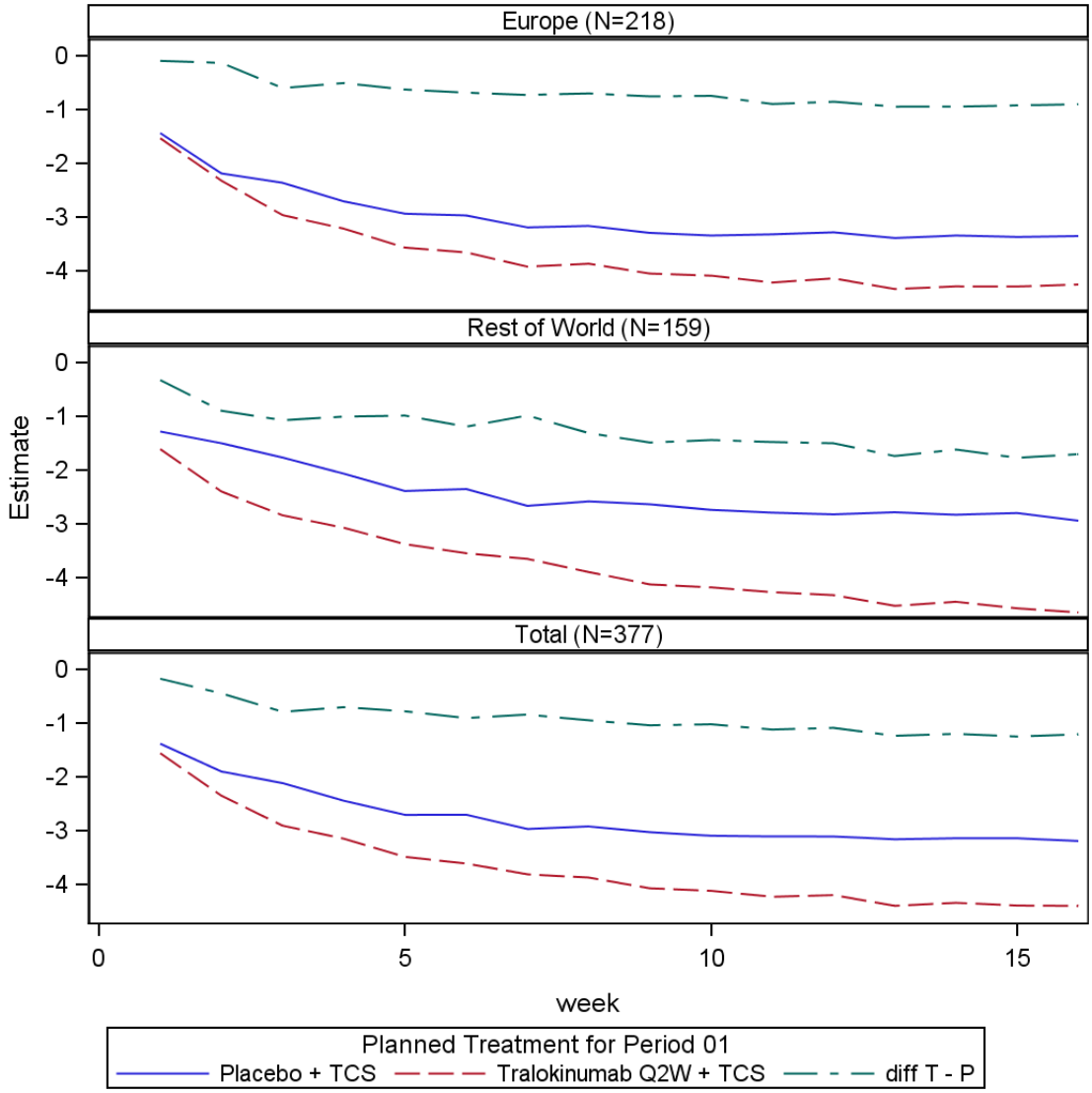
Figure 1.6.295.3.2: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16



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 1.6.297.3.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)		
Week 2		124 51.4 (17.14)			250 46.5 (16.69)		
Week 2 chg		124 -17.3 (16.94)	-16.83 (1.52)		250 -20.5 (14.91)	-20.64 (1.07)	-3.81 (-7.47, -0.15) 0.042 [-0.24 (-0.46, -0.03)]
Week 4		126 46.6 (20.16)			246 40.1 (16.71)		
Week 4 chg		126 -22.3 (19.12)	-21.68 (1.52)		246 -26.9 (15.62)	-26.91 (1.08)	-5.23 (-8.89, -1.57) 0.005 [-0.31 (-0.53, -0.09)]
Week 6		125 43.6 (20.47)			247 35.7 (16.22)		
Week 6 chg		125 -25.2 (18.79)	-24.72 (1.52)		247 -31.2 (15.78)	-31.15 (1.08)	-6.43 (-10.1, -2.76) <.001 [-0.38 (-0.60, -0.16)]
Week 8		122 41.9 (19.17)			243 32.7 (16.17)		
Week 8 chg		122 -26.8 (17.76)	-25.99 (1.53)		243 -34.2 (16.42)	-34.13 (1.08)	-8.15 (-11.8, -4.47) <.001 [-0.48 (-0.70, -0.26)]
Week 10		118 40.4 (20.53)			236 30.2 (16.85)		
Week 10 chg		118 -28.0 (19.22)	-27.39 (1.54)		236 -36.5 (18.20)	-36.38 (1.09)	-8.99 (-12.7, -5.29) <.001 [-0.48 (-0.71, -0.26)]
Week 12		119 39.6 (21.65)			238 29.4 (17.23)		
Week 12 chg		119 -28.8 (20.95)	-28.05 (1.53)		238 -37.6 (18.51)	-37.68 (1.08)	-9.63 (-13.3, -5.94) <.001 [-0.50 (-0.72, -0.27)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1524
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 1.6.297.3.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		118 38.8 (22.39)			235 28.5 (18.20)		
Week 14 chg		118 -29.6 (21.97)	-28.76 (1.54)		235 -38.4 (18.95)	-38.28 (1.09)	-9.52 (-13.2, -5.82) <.001 [-0.48 (-0.70, -0.25)]
Week 16		122 40.9 (23.52)			241 29.4 (18.62)		
Week 16 chg		122 -27.7 (22.50)	-26.84 (1.53)		241 -37.4 (19.31)	-37.43 (1.08)	-10.59 (-14.3, -6.91) <.001 [-0.52 (-0.74, -0.30)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1524
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.

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Table 1.6.297.3.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Europe							
Baseline	72	72 69.8 (13.20)		147	147 68.2 (13.09)		
Week 2		71 49.9 (15.86)			145 48.2 (15.60)		
Week 2 chg		71 -19.8 (17.05)	-19.52 (1.96)		145 -20.1 (14.43)	-20.23 (1.37)	-0.71 (-5.41, 4.00) 0.768 [-0.05 (-0.33, 0.24)]
Week 4		72 45.3 (19.16)			144 40.8 (17.29)		
Week 4 chg		72 -24.5 (18.24)	-24.08 (1.96)		144 -27.5 (15.94)	-27.50 (1.37)	-3.42 (-8.12, 1.28) 0.153 [-0.20 (-0.49, 0.08)]
Week 6		71 41.7 (18.39)			145 36.4 (17.39)		
Week 6 chg		71 -28.0 (18.06)	-27.77 (1.96)		145 -31.8 (16.05)	-31.98 (1.37)	-4.21 (-8.92, 0.50) 0.080 [-0.25 (-0.54, 0.03)]
Week 8		70 39.3 (16.65)			144 33.3 (16.67)		
Week 8 chg		70 -30.4 (15.49)	-29.97 (1.97)		144 -34.9 (15.85)	-34.88 (1.37)	-4.91 (-9.63, -0.19) 0.041 [-0.31 (-0.60, -0.03)]
Week 10		66 38.4 (17.99)			139 30.7 (17.61)		
Week 10 chg		66 -30.8 (17.12)	-30.59 (1.99)		139 -37.4 (17.58)	-37.20 (1.38)	-6.61 (-11.4, -1.85) 0.007 [-0.38 (-0.67, -0.08)]
Week 12		67 39.5 (19.52)			142 30.4 (18.10)		
Week 12 chg		67 -30.0 (18.82)	-29.62 (1.98)		142 -37.7 (18.27)	-37.84 (1.38)	-8.21 (-13.0, -3.47) <.001 [-0.45 (-0.74, -0.15)]
Week 14		67 37.7 (20.66)			138 30.1 (19.55)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1524
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 1.6.297.3.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	67	-31.4 (20.52)	-31.02 (1.98)	138	-38.1 (19.84)	-37.91 (1.38)	-6.90 (-11.7, -2.14) [-0.34 (-0.64, -0.05)]	0.005
Week 16	69	39.3 (21.06)		143	31.3 (19.84)			
Week 16 chg	69	-30.4 (20.17)	-29.75 (1.97)	143	-36.9 (19.51)	-37.00 (1.38)	-7.25 (-12.0, -2.52) [-0.37 (-0.66, -0.08)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1524
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.

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Table 1.6.297.3.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	54	54 67.5 (13.17)		105	105 65.2 (13.36)			
Week 2		53 53.4 (18.67)			105 44.2 (17.91)			
Week 2 chg		53 -13.9 (16.32)	-13.07 (2.37)		105 -21.0 (15.61)	-21.25 (1.69)	-8.18 (-13.9, -2.44) [-0.52 (-0.85, -0.18)]	0.005
Week 4		54 48.3 (21.49)			102 39.0 (15.88)			
Week 4 chg		54 -19.2 (20.01)	-18.28 (2.36)		102 -26.1 (15.20)	-26.14 (1.70)	-7.86 (-13.6, -2.12) [-0.46 (-0.80, -0.13)]	0.007
Week 6		54 46.1 (22.85)			102 34.9 (14.43)			
Week 6 chg		54 -21.4 (19.23)	-20.48 (2.36)		102 -30.3 (15.41)	-30.03 (1.70)	-9.54 (-15.3, -3.80) [-0.57 (-0.90, -0.23)]	0.001
Week 8		52 45.4 (21.78)			99 31.7 (15.44)			
Week 8 chg		52 -22.0 (19.54)	-20.45 (2.38)		99 -33.2 (17.26)	-33.15 (1.71)	-12.70 (-18.5, -6.92) [-0.70 (-1.05, -0.36)]	<.001
Week 10		52 42.9 (23.30)			97 29.6 (15.76)			
Week 10 chg		52 -24.6 (21.27)	-22.87 (2.38)		97 -35.3 (19.07)	-35.33 (1.72)	-12.46 (-18.2, -6.67) [-0.63 (-0.97, -0.28)]	<.001
Week 12		52 39.7 (24.31)			96 27.8 (15.84)			
Week 12 chg		52 -27.1 (23.50)	-25.65 (2.38)		96 -37.3 (18.96)	-37.59 (1.72)	-11.94 (-17.7, -6.15) [-0.58 (-0.92, -0.23)]	<.001
Week 14		51 40.3 (24.61)			97 26.3 (15.92)			

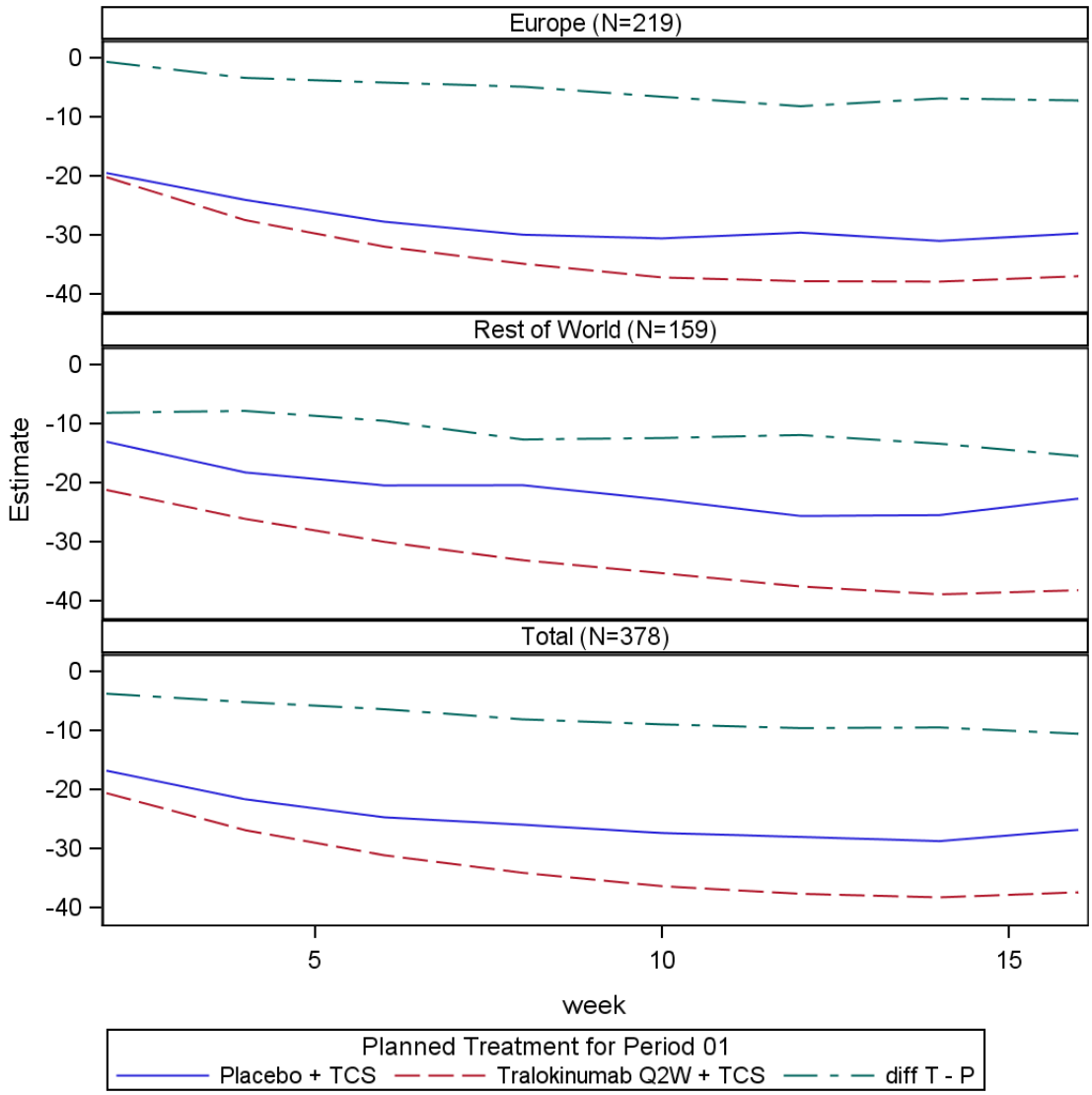
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1524
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.6.297.3.1: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	51	-27.3 (23.74)	-25.50 (2.39)	97	-38.8 (17.71)	-38.91 (1.72)	-13.41 (-19.2, -7.61) [-0.67 (-1.02, -0.32)]	<.001
Week 16	53	43.0 (26.46)		98	26.7 (16.40)			
Week 16 chg	53	-24.2 (24.98)	-22.72 (2.37)	98	-38.1 (19.10)	-38.22 (1.71)	-15.50 (-21.3, -9.73) [-0.73 (-1.07, -0.38)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1524
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 1.6.297.3.2: Total, Region, change in SCORAD, Treatment policy estimand, LP0162-1339, 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 1.6.299.3.1: Total, Region, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score												
Total												
Baseline	126	125	17.2 (7.15)			252	250	17.6 (7.07)				
Week 2		121	9.8 (7.21)				249	8.6 (6.22)				
Week 2 chg		121	-7.3 (6.72)	-7.51	(0.53)		249	-9.0 (7.25)	-8.97	(0.37)	-1.46 (-2.73, -0.19)	0.024
											[-0.21 (-0.42, 0.01)]	
Week 4		122	9.1 (7.39)				245	7.4 (6.28)				
Week 4 chg		122	-8.1 (7.14)	-8.21	(0.53)		245	-10.2 (7.54)	-10.08	(0.37)	-1.87 (-3.14, -0.60)	0.004
											[-0.25 (-0.47, -0.03)]	
Week 6		123	8.4 (6.88)				242	6.3 (5.75)				
Week 6 chg		123	-8.8 (6.70)	-9.03	(0.53)		242	-11.3 (7.41)	-11.01	(0.37)	-1.99 (-3.25, -0.72)	0.002
											[-0.28 (-0.49, -0.06)]	
Week 8		120	8.1 (6.80)				239	6.2 (5.71)				
Week 8 chg		120	-9.1 (7.09)	-9.21	(0.53)		239	-11.6 (7.90)	-11.35	(0.37)	-2.14 (-3.41, -0.87)	0.001
											[-0.28 (-0.50, -0.06)]	
Week 12		116	7.9 (7.06)				227	5.7 (5.50)				
Week 12 chg		116	-9.0 (7.22)	-9.18	(0.53)		227	-11.9 (7.98)	-11.80	(0.38)	-2.62 (-3.90, -1.34)	<.001
											[-0.34 (-0.56, -0.11)]	
Week 16		119	8.4 (7.30)				237	5.7 (6.02)				
Week 16 chg		119	-8.8 (7.09)	-9.07	(0.53)		237	-11.8 (7.57)	-11.70	(0.38)	-2.64 (-3.91, -1.36)	<.001
											[-0.36 (-0.58, -0.13)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8892
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 1.6.299.3.1: Total, Region, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Europe							
Baseline	72	72 16.6 (7.18)		147	146 18.3 (6.85)		
Week 2		71 8.8 (6.81)			145 9.0 (6.44)		
Week 2 chg		71 -7.7 (6.91)	-8.49 (0.68)		145 -9.4 (7.36)	-9.01 (0.47)	-0.52 (-2.16, 1.11) 0.530 [-0.07 (-0.36, 0.21)]
Week 4		71 8.3 (7.00)			144 7.7 (6.19)		
Week 4 chg		71 -8.4 (7.75)	-9.01 (0.68)		144 -10.6 (7.46)	-10.15 (0.48)	-1.15 (-2.78, 0.49) 0.169 [-0.15 (-0.44, 0.13)]
Week 6		70 7.3 (5.94)			141 6.5 (5.62)		
Week 6 chg		70 -9.2 (7.07)	-10.12 (0.68)		141 -11.7 (7.40)	-11.21 (0.48)	-1.09 (-2.73, 0.55) 0.193 [-0.15 (-0.44, 0.14)]
Week 8		70 6.9 (5.22)			143 6.4 (5.97)		
Week 8 chg		70 -9.6 (6.52)	-10.39 (0.68)		143 -12.1 (7.96)	-11.48 (0.48)	-1.09 (-2.73, 0.55) 0.191 [-0.15 (-0.43, 0.14)]
Week 12		66 7.0 (6.30)			135 5.9 (5.67)		
Week 12 chg		66 -9.1 (7.11)	-10.14 (0.69)		135 -12.3 (7.88)	-11.87 (0.48)	-1.74 (-3.40, -0.08) 0.040 [-0.23 (-0.52, 0.07)]
Week 16		68 7.6 (6.65)			141 6.0 (5.86)		
Week 16 chg		68 -9.0 (7.31)	-9.86 (0.68)		141 -12.3 (7.82)	-11.84 (0.48)	-1.98 (-3.62, -0.33) 0.019 [-0.26 (-0.55, 0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8892
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.

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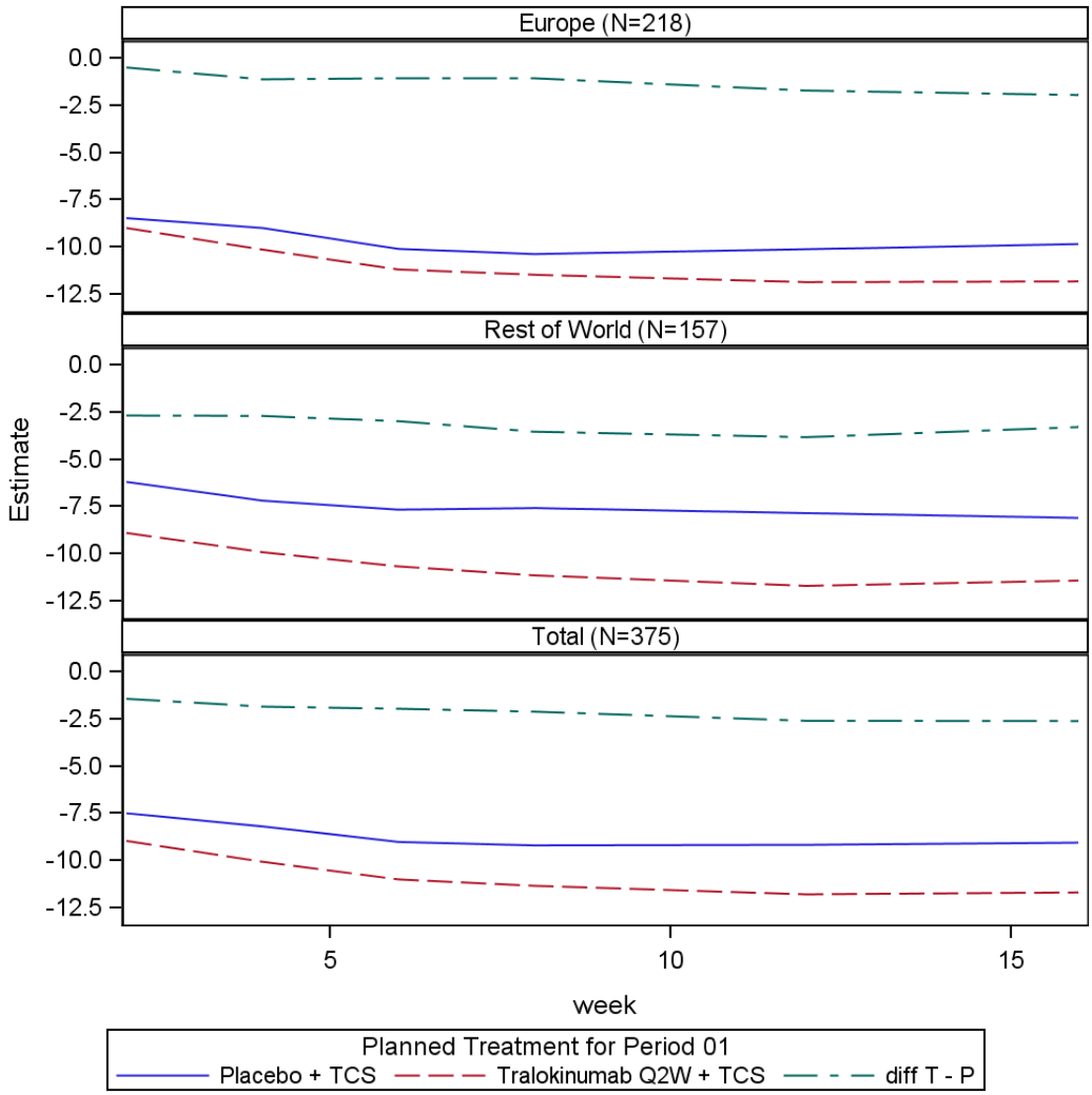
Table 1.6.299.3.1: Total, Region, change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World												
Baseline	54	53	18.0 (7.10)			105	104	16.5 (7.27)				
Week 2		50	11.2 (7.57)				104	7.9 (5.89)				
Week 2 chg		50	-6.6 (6.45)	-6.21	(0.83)		104	-8.6 (7.10)	-8.91	(0.58)	-2.70 (-4.69, -0.70) [-0.39 (-0.73, -0.05)]	0.008
Week 4		51	10.3 (7.82)				101	6.9 (6.41)				
Week 4 chg		51	-7.7 (6.24)	-7.20	(0.82)		101	-9.7 (7.66)	-9.93	(0.59)	-2.72 (-4.72, -0.73) [-0.38 (-0.72, -0.04)]	0.008
Week 6		53	9.8 (7.78)				101	6.1 (5.95)				
Week 6 chg		53	-8.2 (6.18)	-7.68	(0.82)		101	-10.6 (7.41)	-10.68	(0.59)	-3.00 (-4.99, -1.02) [-0.43 (-0.76, -0.09)]	0.003
Week 8		50	9.8 (8.29)				96	5.8 (5.30)				
Week 8 chg		50	-8.4 (7.84)	-7.60	(0.83)		96	-11.0 (7.80)	-11.16	(0.59)	-3.56 (-5.56, -1.55) [-0.46 (-0.80, -0.11)]	<.001
Week 12		50	9.1 (7.86)				92	5.3 (5.26)				
Week 12 chg		50	-8.8 (7.43)	-7.86	(0.83)		92	-11.2 (8.13)	-11.71	(0.60)	-3.85 (-5.86, -1.84) [-0.49 (-0.84, -0.14)]	<.001
Week 16		51	9.4 (8.03)				96	5.4 (6.26)				
Week 16 chg		51	-8.5 (6.86)	-8.12	(0.82)		96	-11.1 (7.17)	-11.43	(0.59)	-3.32 (-5.32, -1.31) [-0.47 (-0.81, -0.13)]	0.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8892
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 1.6.299.3.2: Total, Region, change in DLQI, Treatment policy estimand, LP0162-1339, 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 1.6.300.3.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total												
Total												
Baseline	126	124	22.4 (5.63)			252	250	22.3 (5.09)				
Week 2		120	16.2 (7.55)				248	14.4 (6.85)				
Week 2 chg		120	-6.1 (6.67)	-6.14	(0.61)		248	-7.8 (6.57)	-7.88	(0.42)	-1.74 (-3.19, -0.29) [-0.26 (-0.48, -0.04)]	0.019
Week 4		121	15.5 (7.82)				244	12.5 (6.95)				
Week 4 chg		121	-6.8 (7.00)	-6.89	(0.60)		244	-9.8 (7.02)	-9.82	(0.43)	-2.94 (-4.39, -1.48) [-0.42 (-0.64, -0.20)]	<.001
Week 6		122	14.7 (7.89)				242	11.4 (6.75)				
Week 6 chg		122	-7.7 (7.44)	-7.68	(0.60)		242	-10.9 (6.87)	-10.80	(0.43)	-3.12 (-4.57, -1.66) [-0.44 (-0.66, -0.22)]	<.001
Week 8		119	14.6 (7.88)				239	11.2 (7.08)				
Week 8 chg		119	-7.7 (7.38)	-7.60	(0.61)		239	-11.1 (7.24)	-11.05	(0.43)	-3.45 (-4.91, -1.99) [-0.47 (-0.70, -0.25)]	<.001
Week 12		115	14.0 (8.12)				227	10.6 (6.62)				
Week 12 chg		115	-8.2 (7.71)	-7.99	(0.61)		227	-11.6 (6.72)	-11.65	(0.43)	-3.67 (-5.14, -2.20) [-0.52 (-0.75, -0.29)]	<.001
Week 16		118	14.7 (8.27)				237	10.5 (7.20)				
Week 16 chg		118	-7.8 (7.40)	-7.85	(0.61)		237	-11.7 (7.37)	-11.68	(0.43)	-3.83 (-5.28, -2.37) [-0.52 (-0.74, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9617
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 1.6.300.3.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Europe								
Baseline	72	71 22.0 (5.89)		147	146 23.0 (4.66)			
Week 2		70 16.1 (7.46)			145 15.2 (6.69)			
Week 2 chg		70 -5.9 (6.44)	-6.16 (0.78)		145 -7.7 (6.31)	-7.62 (0.54)	-1.46 (-3.33, 0.40) [-0.23 (-0.52, 0.06)]	0.124
Week 4		70 15.3 (8.02)			144 13.2 (6.75)			
Week 4 chg		70 -6.7 (7.21)	-6.94 (0.78)		144 -9.8 (6.58)	-9.67 (0.54)	-2.73 (-4.59, -0.86) [-0.40 (-0.69, -0.11)]	0.004
Week 6		69 14.2 (7.57)			141 11.9 (6.54)			
Week 6 chg		69 -7.8 (7.69)	-8.12 (0.78)		141 -11.0 (6.62)	-10.83 (0.54)	-2.71 (-4.58, -0.84) [-0.39 (-0.68, -0.10)]	0.005
Week 8		69 14.2 (7.42)			143 11.7 (6.82)			
Week 8 chg		69 -7.7 (7.38)	-8.09 (0.78)		143 -11.3 (7.10)	-11.08 (0.54)	-2.99 (-4.86, -1.12) [-0.42 (-0.71, -0.13)]	0.002
Week 12		65 13.5 (7.47)			135 11.0 (6.43)			
Week 12 chg		65 -8.3 (7.55)	-8.53 (0.79)		135 -11.8 (6.75)	-11.55 (0.55)	-3.02 (-4.91, -1.13) [-0.43 (-0.73, -0.13)]	0.002
Week 16		67 14.3 (7.86)			141 11.2 (6.94)			
Week 16 chg		67 -8.0 (7.43)	-8.21 (0.78)		141 -11.7 (7.14)	-11.54 (0.54)	-3.33 (-5.21, -1.46) [-0.46 (-0.75, -0.17)]	<.001

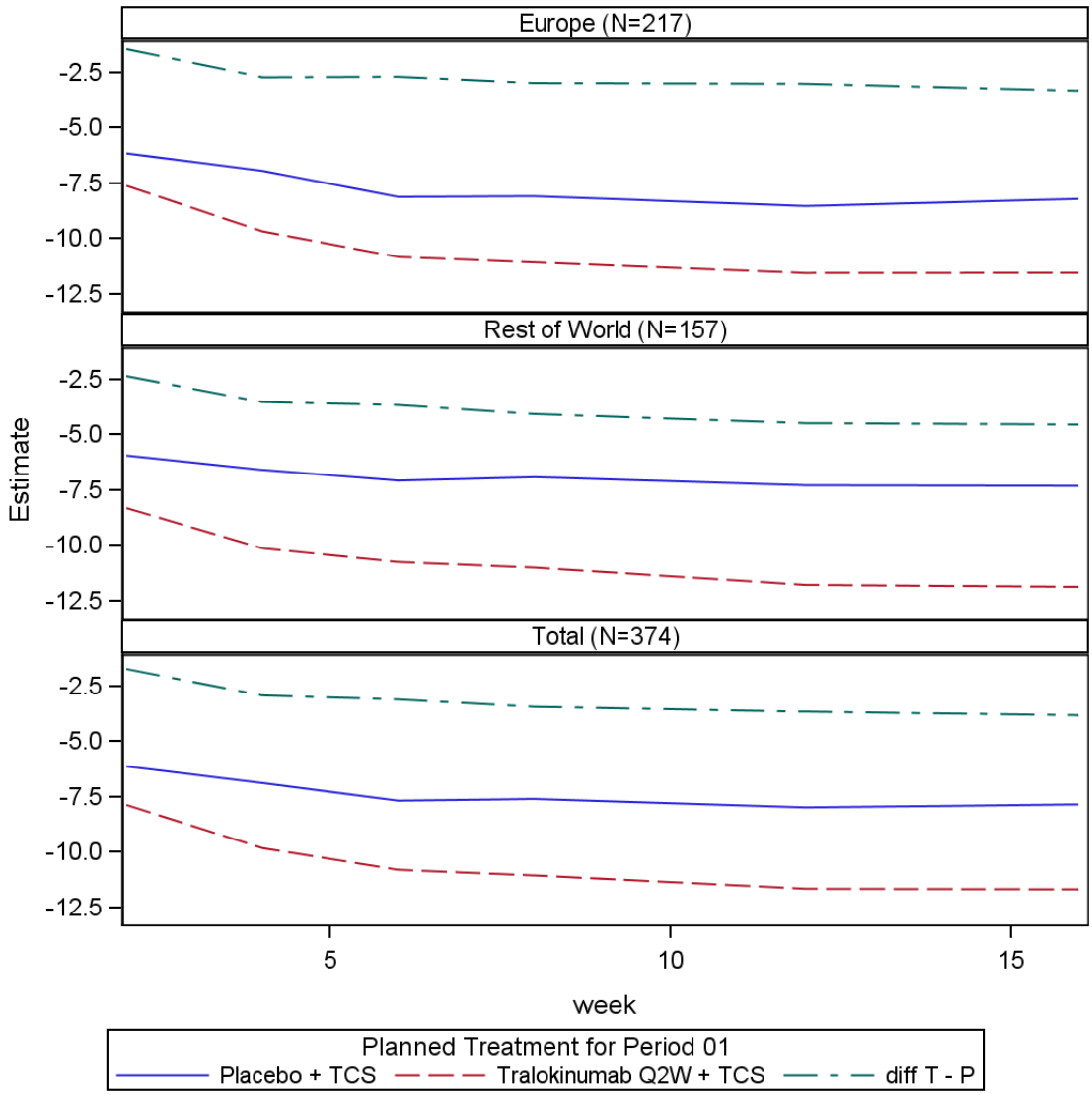
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9617
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.6.300.3.1: Total, Region, change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World										
Baseline	54	53	22.8 (5.27)		105	104	21.3 (5.52)			
Week 2		50	16.3 (7.75)			103	13.3 (6.93)			
Week 2 chg		50	-6.3 (7.04)	-5.95 (0.96)		103	-8.0 (6.94)	-8.32 (0.68)	-2.37 (-4.69, -0.05) [-0.34 (-0.68, 0.00)]	0.046
Week 4		51	15.7 (7.61)			100	11.4 (7.14)			
Week 4 chg		51	-7.1 (6.77)	-6.60 (0.96)		100	-9.8 (7.64)	-10.13 (0.68)	-3.54 (-5.86, -1.21) [-0.48 (-0.82, -0.14)]	0.003
Week 6		53	15.3 (8.32)			101	10.7 (7.01)			
Week 6 chg		53	-7.6 (7.18)	-7.08 (0.95)		101	-10.7 (7.23)	-10.76 (0.68)	-3.67 (-5.99, -1.36) [-0.51 (-0.85, -0.17)]	0.002
Week 8		50	15.3 (8.52)			96	10.6 (7.45)			
Week 8 chg		50	-7.6 (7.46)	-6.93 (0.96)		96	-10.7 (7.48)	-11.01 (0.69)	-4.08 (-6.42, -1.74) [-0.55 (-0.89, -0.20)]	<.001
Week 12		50	14.7 (8.92)			92	9.9 (6.87)			
Week 12 chg		50	-7.9 (7.98)	-7.29 (0.96)		92	-11.4 (6.70)	-11.79 (0.69)	-4.49 (-6.84, -2.15) [-0.63 (-0.98, -0.27)]	<.001
Week 16		51	15.1 (8.85)			96	9.5 (7.49)			
Week 16 chg		51	-7.7 (7.43)	-7.32 (0.96)		96	-11.6 (7.74)	-11.87 (0.69)	-4.56 (-6.89, -2.22) [-0.60 (-0.94, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9617
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 1.6.300.3.2: Total, Region, change in POEM, Treatment policy estimand, LP0162-1339, 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 1.6.318.3.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss										
Total										
Baseline	126	126	6.9 (2.72)		252	252	6.5 (2.77)			
Week 2		124	4.4 (3.05)			250	3.7 (2.95)			
Week 2 chg		124	-2.5 (2.93)	-2.39 (0.24)		250	-2.8 (2.95)	-2.85 (0.17)	-0.46 (-1.03, 0.11) [-0.16 (-0.37, 0.06)]	0.115
Week 4		126	3.7 (3.07)			246	3.1 (2.84)			
Week 4 chg		126	-3.1 (3.14)	-2.96 (0.24)		246	-3.3 (3.01)	-3.36 (0.17)	-0.40 (-0.97, 0.17) [-0.13 (-0.35, 0.08)]	0.167
Week 6		125	3.4 (2.99)			247	2.7 (2.75)			
Week 6 chg		125	-3.5 (3.05)	-3.31 (0.24)		247	-3.7 (3.04)	-3.71 (0.17)	-0.40 (-0.97, 0.17) [-0.13 (-0.35, 0.08)]	0.166
Week 8		122	3.4 (3.15)			243	2.5 (2.71)			
Week 8 chg		122	-3.4 (3.28)	-3.26 (0.24)		243	-3.9 (2.98)	-3.97 (0.17)	-0.71 (-1.28, -0.14) [-0.23 (-0.45, -0.01)]	0.015
Week 10		118	3.2 (2.97)			236	2.3 (2.60)			
Week 10 chg		118	-3.6 (3.11)	-3.48 (0.24)		236	-4.1 (3.15)	-4.17 (0.17)	-0.70 (-1.27, -0.12) [-0.22 (-0.44, -0.00)]	0.017
Week 12		119	3.1 (3.11)			238	2.2 (2.57)			
Week 12 chg		119	-3.7 (3.14)	-3.54 (0.24)		238	-4.2 (3.15)	-4.25 (0.17)	-0.71 (-1.29, -0.14) [-0.23 (-0.45, -0.01)]	0.015

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3604
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 VAS = Treatment*Week + [Baseline VAS]*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 1.6.318.3.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	3.0 (3.03)		235	2.0 (2.52)			
Week 14 chg	118	-3.8 (3.10)	-3.60 (0.24)	235	-4.4 (3.19)	-4.42 (0.17)	-0.82 (-1.39, -0.24) [-0.26 (-0.48, -0.04)]	0.005
Week 16	122	3.2 (3.24)		241	2.2 (2.68)			
Week 16 chg	122	-3.7 (3.20)	-3.46 (0.24)	241	-4.2 (3.34)	-4.27 (0.17)	-0.80 (-1.38, -0.23) [-0.24 (-0.46, -0.03)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3604
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 VAS = Treatment*Week + [Baseline VAS]*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.

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Table 1.6.318.3.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Europe								
Baseline	72	72 6.4 (2.82)		147	147 6.3 (2.76)			
Week 2		71 3.8 (2.85)			145 3.8 (2.92)			
Week 2 chg		71 -2.5 (2.84)	-2.57 (0.30)		145 -2.5 (2.65)	-2.51 (0.21)	0.06 (-0.65, 0.77) [0.02 (-0.26, 0.31)]	0.865
Week 4		72 3.3 (2.83)			144 3.1 (2.83)			
Week 4 chg		72 -3.1 (3.17)	-3.04 (0.29)		144 -3.2 (2.80)	-3.18 (0.21)	-0.14 (-0.85, 0.57) [-0.05 (-0.33, 0.24)]	0.702
Week 6		71 2.8 (2.64)			145 2.8 (2.75)			
Week 6 chg		71 -3.6 (3.04)	-3.60 (0.30)		145 -3.6 (2.87)	-3.54 (0.21)	0.06 (-0.65, 0.77) [0.02 (-0.26, 0.30)]	0.870
Week 8		70 3.0 (2.77)			144 2.5 (2.66)			
Week 8 chg		70 -3.4 (3.07)	-3.39 (0.30)		144 -3.9 (2.86)	-3.81 (0.21)	-0.42 (-1.13, 0.29) [-0.14 (-0.43, 0.14)]	0.246
Week 10		66 2.8 (2.75)			139 2.2 (2.54)			
Week 10 chg		66 -3.5 (3.14)	-3.59 (0.30)		139 -4.1 (2.97)	-4.03 (0.21)	-0.45 (-1.16, 0.27) [-0.15 (-0.44, 0.15)]	0.224
Week 12		67 2.8 (2.82)			142 2.3 (2.72)			
Week 12 chg		67 -3.5 (2.98)	-3.58 (0.30)		142 -4.0 (3.07)	-3.97 (0.21)	-0.39 (-1.10, 0.33) [-0.13 (-0.42, 0.16)]	0.289
Week 14		67 2.8 (2.93)			138 2.1 (2.61)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3604
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 VAS = Treatment*Week + [Baseline VAS]*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 1.6.318.3.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	67	-3.4 (3.00)	-3.52 (0.30)	138	-4.2 (3.02)	-4.08 (0.21)	-0.55 (-1.27, 0.16) [-0.18 (-0.48, 0.11)]	0.129
Week 16	69	2.8 (2.94)		143	2.3 (2.79)			
Week 16 chg	69	-3.5 (3.04)	-3.54 (0.30)	143	-4.0 (3.19)	-3.96 (0.21)	-0.43 (-1.14, 0.28) [-0.14 (-0.42, 0.15)]	0.239

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3604
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 VAS = Treatment*Week + [Baseline VAS]*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 1.6.318.3.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World												
Baseline	54	54	7.6 (2.42)			105	105	6.6 (2.79)				
Week 2		53	5.1 (3.17)				105	3.4 (3.00)				
Week 2 chg		53	-2.5 (3.08)	-2.09	(0.39)		105	-3.2 (3.28)	-3.36	(0.27)	-1.27 (-2.21, -0.33) [-0.40 (-0.73, -0.06)]	0.008
Week 4		54	4.4 (3.30)				102	3.1 (2.88)				
Week 4 chg		54	-3.2 (3.13)	-2.81	(0.39)		102	-3.5 (3.30)	-3.63	(0.28)	-0.81 (-1.75, 0.13) [-0.25 (-0.58, 0.08)]	0.091
Week 6		54	4.3 (3.23)				102	2.7 (2.77)				
Week 6 chg		54	-3.3 (3.08)	-2.90	(0.39)		102	-3.9 (3.27)	-3.96	(0.28)	-1.06 (-2.00, -0.12) [-0.33 (-0.66, 0.00)]	0.028
Week 8		52	4.1 (3.53)				99	2.5 (2.81)				
Week 8 chg		52	-3.5 (3.56)	-3.06	(0.39)		99	-4.0 (3.17)	-4.19	(0.28)	-1.13 (-2.08, -0.18) [-0.34 (-0.68, -0.00)]	0.020
Week 10		52	3.8 (3.17)				97	2.3 (2.69)				
Week 10 chg		52	-3.8 (3.08)	-3.31	(0.39)		97	-4.2 (3.41)	-4.38	(0.28)	-1.07 (-2.02, -0.12) [-0.32 (-0.66, 0.01)]	0.027
Week 12		52	3.6 (3.42)				96	2.1 (2.34)				
Week 12 chg		52	-4.0 (3.35)	-3.43	(0.39)		96	-4.4 (3.27)	-4.69	(0.28)	-1.26 (-2.21, -0.30) [-0.38 (-0.72, -0.04)]	0.010
Week 14		51	3.3 (3.16)				97	1.8 (2.39)				

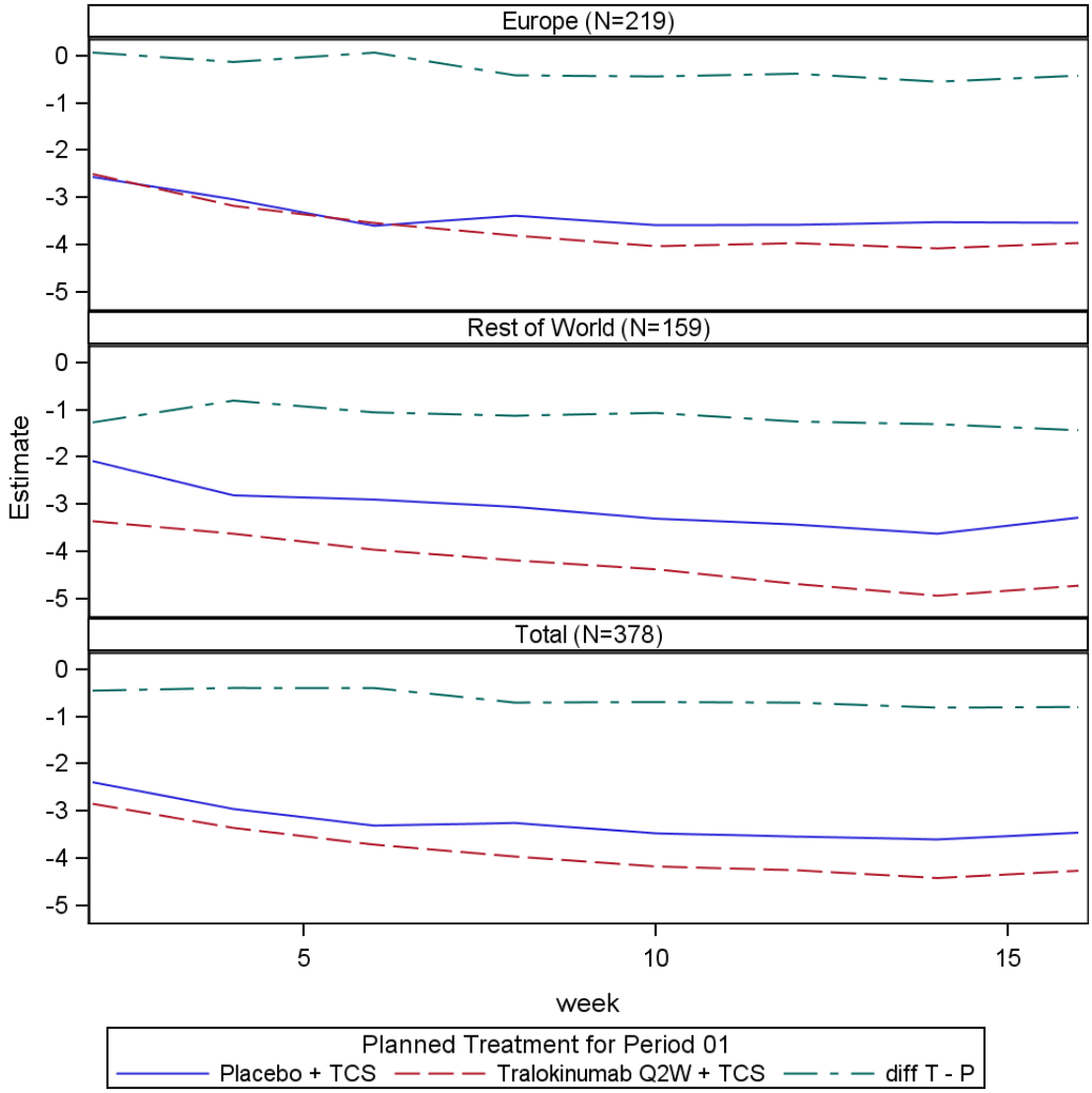
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3604
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*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 1.6.318.3.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	51	-4.2 (3.21)	-3.63 (0.39)	97	-4.6 (3.40)	-4.94 (0.28)	-1.31 (-2.26, -0.36) [-0.39 (-0.73, -0.05)]	0.007
Week 16	53	3.7 (3.55)		98	2.0 (2.51)			
Week 16 chg	53	-3.9 (3.42)	-3.29 (0.39)	98	-4.5 (3.54)	-4.72 (0.28)	-1.44 (-2.39, -0.49) [-0.41 (-0.75, -0.07)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3604
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 VAS = Treatment*Week + [Baseline VAS]*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 1.6.318.3.2: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 1.6.319.3.1: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	126	125	59.4 (23.09)		252	250	59.1 (25.01)		
Week 4		122	70.1 (18.94)			249	74.1 (18.34)		
Week 4 chg		122	10.3 (18.72)	11.01 (1.54)		249	15.0 (21.76)	15.00 (1.09)	3.99 (0.28, 7.69) 0.035 [0.19 (-0.03, 0.41)]
Week 8		120	71.2 (20.22)			237	75.5 (18.26)		
Week 8 chg		120	12.1 (23.42)	12.22 (1.55)		237	16.4 (23.73)	16.03 (1.10)	3.81 (0.07, 7.55) 0.046 [0.16 (-0.06, 0.38)]
Week 12		116	72.3 (21.36)			227	75.1 (18.28)		
Week 12 chg		116	12.1 (23.53)	12.65 (1.57)		227	16.4 (23.72)	15.70 (1.12)	3.04 (-0.74, 6.83) 0.115 [0.13 (-0.10, 0.35)]
Week 16		116	71.5 (21.22)			232	75.8 (18.84)		
Week 16 chg		116	12.4 (22.66)	12.51 (1.57)		232	17.0 (24.19)	16.27 (1.11)	3.77 (-0.01, 7.55) 0.051 [0.16 (-0.06, 0.38)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4029
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 VAS = Treatment*Week + [Baseline VAS]*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 1.6.319.3.1: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Europe							
Baseline	72	72 52.8 (21.62)		147	146 50.0 (23.89)		
Week 4		71 67.9 (17.67)			146 70.4 (17.86)		
Week 4 chg		71 14.7 (21.24)	16.22 (2.09)		146 20.4 (23.28)	19.55 (1.46)	3.32 (-1.70, 8.35) 0.194 [0.15 (-0.14, 0.43)]
Week 8		70 71.0 (17.48)			141 71.4 (19.09)		
Week 8 chg		70 18.1 (21.46)	19.15 (2.10)		141 20.4 (26.01)	19.74 (1.48)	0.58 (-4.47, 5.64) 0.820 [0.02 (-0.26, 0.31)]
Week 12		66 70.1 (20.43)			135 71.3 (18.29)		
Week 12 chg		66 17.2 (22.99)	18.27 (2.14)		135 20.7 (25.45)	19.80 (1.50)	1.53 (-3.61, 6.66) 0.559 [0.06 (-0.23, 0.36)]
Week 16		66 71.1 (18.15)			139 72.3 (19.29)		
Week 16 chg		66 18.5 (21.63)	19.32 (2.14)		139 21.7 (26.46)	20.45 (1.48)	1.14 (-3.98, 6.26) 0.663 [0.05 (-0.25, 0.34)]

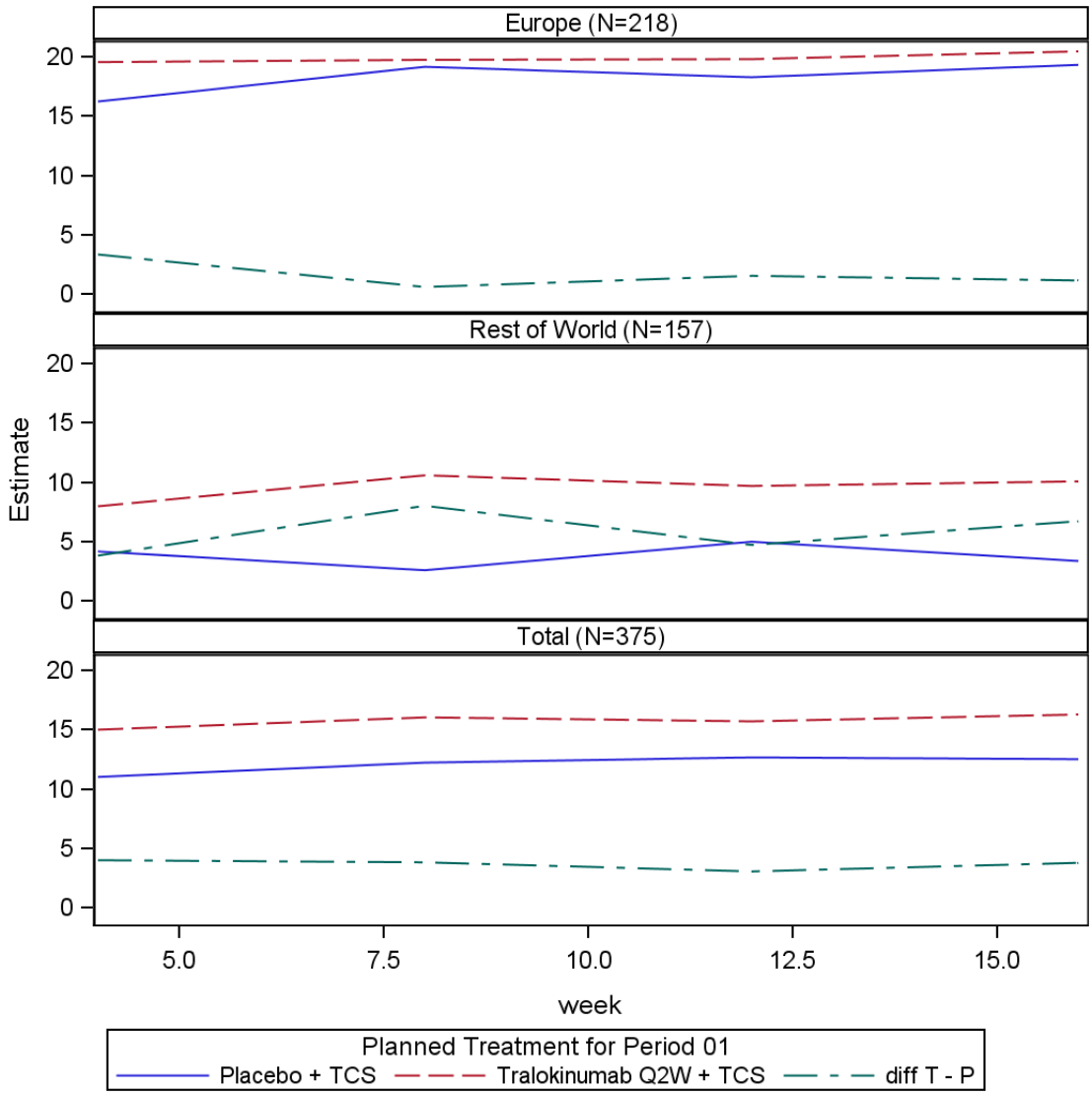
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4029
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*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 1.6.319.3.1: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World									
Baseline	54	53	68.4 (22.15)		105	104	71.9 (20.60)		
Week 4		51	73.1 (20.36)			103	79.3 (17.84)		
Week 4 chg		51	4.3 (12.35)	4.16 (2.22)		103	7.2 (16.65)	7.96 (1.57)	3.81 (-1.55, 9.17) 0.163 [0.25 (-0.09, 0.58)]
Week 8		50	71.4 (23.73)			96	81.7 (15.08)		
Week 8 chg		50	3.7 (23.67)	2.57 (2.24)		96	10.5 (18.50)	10.58 (1.61)	8.01 (2.57, 13.45) 0.004 [0.39 (0.05, 0.74)]
Week 12		50	75.3 (22.41)			92	80.5 (16.93)		
Week 12 chg		50	5.2 (22.68)	4.97 (2.24)		92	10.2 (19.41)	9.68 (1.64)	4.70 (-0.75, 10.16) 0.091 [0.23 (-0.12, 0.57)]
Week 16		50	72.0 (24.88)			93	81.2 (16.89)		
Week 16 chg		50	4.3 (21.61)	3.35 (2.24)		93	10.0 (18.36)	10.06 (1.63)	6.71 (1.25, 12.17) 0.016 [0.34 (-0.00, 0.69)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4029
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 VAS = Treatment*Week + [Baseline VAS]*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 1.6.319.3.2: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 1.6.444.3.1: Total, Region, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	126	126 30.4 (12.78)		252	252 28.8 (11.97)		
Week 16		123 14.1 (14.89)			241 8.1 (9.15)		
Week 16 chg		123 -16.0 (14.04)	-15.43 (0.94)		241 -20.7 (12.33)	-20.93 (0.67)	-5.50 (-7.79, -3.22) <.001 [-0.43 (-0.64, -0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0669
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.444.3.1: Total, Region, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Europe							
Baseline	72	72 32.0 (13.61)		147	147 30.7 (12.07)		
Week 16		70 13.1 (14.38)			143 9.0 (10.14)		
Week 16 chg		70 -18.6 (13.74)	-18.19 (1.28)		143 -21.6 (12.98)	-21.85 (0.89)	-3.67 (-6.74, -0.59) 0.020 [-0.28 (-0.56, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0669
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.444.3.1: Total, Region, change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	54	54 28.3 (11.36)		105	105 26.2 (11.37)			
Week 16		53 15.3 (15.59)			98 6.6 (7.27)			
Week 16 chg		53 -12.5 (13.80)	-11.61 (1.38)		98 -19.2 (11.23)	-19.70 (1.01)	-8.10 (-11.5, -4.71) [-0.66 (-1.01, -0.32)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0669
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.6.701.3.1: Total, Any TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.9406	0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504
Europe		0.4698	1.05 (0.91, 1.22)	1.30 (0.64, 2.61)	4.1 (-7.3, 15.5)	56	(77.8)	133	120	(81.6)	351
Rest of World		0.5041	1.11 (0.82, 1.49)	1.26 (0.64, 2.48)	5.5 (-10, 21.4)	28	(51.9)	51	60	(57.1)	153

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 1.6.702.3.1: Total, Any drug-related TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.9077	0.0023	1.58 (1.16, 2.16)	2.11 (1.30, 3.42)	15.7 (6.11, 25.2)	34	(27.0)	61	108	(42.9)	232
Europe		0.0141	1.49 (1.06, 2.10)	2.07 (1.16, 3.69)	17.7 (4.02, 31.4)	26	(36.1)	51	79	(53.7)	176
Rest of World		0.0710	1.87 (0.92, 3.80)	2.21 (0.93, 5.25)	12.8 (0.11, 25.6)	8	(14.8)	10	29	(27.6)	56

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 1.6.703.3.1: Total, Any TEAE causing permanent discontinuation, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Europe						72 21.5		147 44.1	
Rest of World						54 16.4		105 30.9	
Any system organ class									
Any preferred term									
Total	0.3829	0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1 (0.8)	1	6 (2.4)	8
Europe		0.5186	2.02 (0.23, 17.8)	2.06 (0.22, 19.1)	1.4 (-2.4, 5.15)	1 (1.4)	1	4 (2.7)	4
Rest of World		0.3111			1.9 (-.72, 4.49)	0 (0.0)	0	2 (1.9)	4

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 1.6.704.3.1: Total, Any mild TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.6669	0.1405	1.14 (0.95, 1.36)	1.41 (0.89, 2.23)	7.5 (-2.5, 17.5)	69	(54.8)	132	157	(62.3)	384
Europe		0.4230	1.08 (0.89, 1.29)	1.29 (0.69, 2.40)	5.1 (-7.7, 18.0)	49	(68.1)	102	107	(72.8)	264
Rest of World		0.1946	1.29 (0.87, 1.92)	1.57 (0.79, 3.11)	10.7 (-5.1, 26.5)	20	(37.0)	30	50	(47.6)	120

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 1.6.705.3.1: Total, Any moderate TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.1870	0.6376	1.09 (0.75, 1.59)	1.13 (0.68, 1.85)	2.2 (-7.0, 11.4)	30	(23.8)	42	66	(26.2)	113
Europe		0.2549	1.30 (0.81, 2.08)	1.44 (0.77, 2.70)	7.5 (-5.1, 20.2)	18	(25.0)	25	48	(32.7)	80
Rest of World		0.4450	0.78 (0.41, 1.48)	0.72 (0.32, 1.66)	-5.0 (-18, 8.12)	12	(22.2)	17	18	(17.1)	33

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 1.6.706.3.1: Total, Any severe TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.0270	0.1738	0.50 (0.18, 1.39)	0.48 (0.16, 1.41)	-2.8 (-7.3, 1.68)	7	(5.6)	10	7	(2.8)	7
Europe		0.8039	0.86 (0.26, 2.83)	0.85 (0.24, 3.01)	-0.8 (-7.1, 5.54)	4	(5.6)	6	7	(4.8)	7
Rest of World		0.0156	0.00 (not est.)	0.00 (not est.)	-5.5 (-12, 0.56)	3	(5.6)	4	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. TEAE: Treatment emergent adverse events

Table 1.6.707.3.1: Total, Death, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Europe					72	21.5		147	44.1	
Rest of World					54	16.4		105	30.9	

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.

Table 1.6.708.3.1: Total, Any TE SAE, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Europe						72 21.5		147 44.1	
Rest of World						54 16.4		105 30.9	
Any system organ class									
Any preferred term									
Total	0.3527	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4 (3.2)	4	2 (0.8)	2
Europe		0.1878	0.32 (0.05, 1.93)	0.31 (0.05, 1.93)	-2.8 (-7.8, 2.14)	3 (4.2)	3	2 (1.4)	2
Rest of World		0.1675	0.00 (not est.)	0.00 (not est.)	-1.8 (-5.4, 1.74)	1 (1.9)	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. TE SAE: Treatment emergent serious adverse events

Table 1.6.709.3.1: Total, Any drug-related TE SAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Europe					72	21.5		147	44.1	
Rest of World					54	16.4		105	30.9	

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 1.6.710.3.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Europe					72	21.5		147	44.1	
Rest of World					54	16.4		105	30.9	

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 1.6.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.9406	0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504
Europe		0.4698	1.05 (0.91, 1.22)	1.30 (0.64, 2.61)	4.1 (-7.3, 15.5)	56	(77.8)	133	120	(81.6)	351
Rest of World		0.5041	1.11 (0.82, 1.49)	1.26 (0.64, 2.48)	5.5 (-10, 21.4)	28	(51.9)	51	60	(57.1)	153
Eye disorders											
Any											
Total	0.2033	0.0191	3.12 (1.12, 8.68)	3.50 (1.17, 10.5)	6.7 (2.02, 11.5)	4	(3.2)	5	25	(9.9)	29
Europe		0.0683	2.49 (0.89, 6.99)	2.76 (0.90, 8.45)	8.2 (0.59, 15.8)	4	(5.6)	5	20	(13.6)	24
Rest of World		0.1055			4.7 (0.68, 8.81)	0	(0.0)	0	5	(4.8)	5
Gastrointestinal disorders											
Any											
Total	0.4821	0.2711	1.49 (0.73, 3.06)	1.55 (0.71, 3.40)	3.5 (-2.4, 9.43)	9	(7.1)	10	27	(10.7)	30
General disorders and administration site conditions											
Any											
Total	0.8077	0.0459	1.81 (0.99, 3.31)	1.99 (1.00, 3.94)	7.7 (0.80, 14.6)	12	(9.5)	13	43	(17.1)	66
Europe		0.1734	1.71 (0.78, 3.75)	1.86 (0.76, 4.59)	6.8 (-2.2, 15.8)	7	(9.7)	8	24	(16.3)	35
Rest of World		0.1407	1.96 (0.77, 4.99)	2.17 (0.76, 6.20)	8.9 (-1.8, 19.6)	5	(9.3)	5	19	(18.1)	31

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 1.6.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Injection site reaction											
Total	1.0000	0.0026			6.7 (3.63, 9.81)	0	(0.0)	0	17	(6.7)	30
Europe		0.1200			3.3 (0.40, 6.17)	0	(0.0)	0	5	(3.4)	11
Rest of World		0.0099			11.4 (5.30, 17.4)	0	(0.0)	0	12	(11.4)	19
Infections and infestations											
Any											
Total	0.2975	0.0346	1.30 (1.01, 1.69)	1.63 (1.03, 2.56)	11.1 (0.97, 21.2)	46	(36.5)	72	120	(47.6)	186
Europe		0.0213	1.38 (1.03, 1.86)	1.97 (1.11, 3.51)	16.5 (2.68, 30.2)	31	(43.1)	51	87	(59.2)	142
Rest of World		0.6220	1.14 (0.68, 1.89)	1.20 (0.58, 2.50)	3.8 (-11, 18.5)	15	(27.8)	21	33	(31.4)	44
Upper respiratory tract infection											
Total	0.4374	0.3271	1.55 (0.64, 3.79)	1.60 (0.62, 4.11)	2.6 (-2.3, 7.57)	6	(4.8)	7	19	(7.5)	21
Conjunctivitis											
Total	0.3724	0.0087	3.46 (1.25, 9.58)	3.95 (1.33, 11.7)	7.8 (2.97, 12.7)	4	(3.2)	4	28	(11.1)	32
Europe		0.0195	3.07 (1.10, 8.56)	3.48 (1.16, 10.4)	11.4 (3.39, 19.5)	4	(5.6)	4	25	(17.0)	29
Rest of World		0.2018			2.9 (-.31, 6.10)	0	(0.0)	0	3	(2.9)	3
Viral upper respiratory tract infection											
Total	0.7317	0.0363	1.75 (1.02, 3.01)	2.00 (1.04, 3.85)	8.3 (1.16, 15.4)	14	(11.1)	18	49	(19.4)	64
Europe		0.0438	1.80 (0.99, 3.29)	2.14 (1.02, 4.52)	12.2 (1.36, 23.1)	11	(15.3)	15	40	(27.2)	52
Rest of World		0.5011	1.54 (0.43, 5.44)	1.59 (0.41, 6.14)	3.0 (-5.1, 11.1)	3	(5.6)	3	9	(8.6)	12
Injury, poisoning and procedural complications											
Any											
Total	0.7278	0.5974	1.31 (0.48, 3.60)	1.32 (0.46, 3.77)	1.2 (-3.2, 5.63)	5	(4.0)	6	13	(5.2)	14
Musculoskeletal and connective tissue disorders											
Any											

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 1.6.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Total	0.6999	0.2269	1.79 (0.68, 4.68)	1.86 (0.67, 5.14)	3.2 (-1.5, 7.81)	5 (4.0)	6	18 (7.1)	20
Nervous system disorders									
Any									
Total	0.7451	0.1130	1.80 (0.85, 3.78)	1.93 (0.85, 4.40)	5.1 (-.65, 10.8)	8 (6.3)	11	29 (11.5)	37
Headache									
Total	0.2128	0.1663	1.81 (0.77, 4.29)	1.93 (0.75, 4.95)	3.9 (-1.1, 8.91)	6 (4.8)	9	22 (8.7)	26
Respiratory, thoracic and mediastinal disorders									
Any									
Total	0.1357	0.5541	1.21 (0.64, 2.28)	1.24 (0.61, 2.50)	2.0 (-4.5, 8.52)	12 (9.5)	14	29 (11.5)	39
Skin and subcutaneous tissue disorders									
Any									
Total	0.3531	0.0628	0.63 (0.38, 1.02)	0.58 (0.32, 1.03)	-7.1 (-15, 0.81)	24 (19.0)	28	30 (11.9)	36
Dermatitis atopic									
Total	0.8188	0.0125	0.30 (0.11, 0.82)	0.28 (0.10, 0.80)	-5.5 (-11, -.44)	10 (7.9)	12	6 (2.4)	8
Europe		0.0665	0.33 (0.09, 1.14)	0.31 (0.08, 1.14)	-5.5 (-12, 1.35)	6 (8.3)	6	4 (2.7)	6
Rest of World		0.0873	0.26 (0.05, 1.37)	0.24 (0.04, 1.37)	-5.5 (-13, 1.96)	4 (7.4)	6	2 (1.9)	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. TEAE: Treatment emergent adverse events

Table 1.6.712.3.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.3527	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4	(3.2)	4	2	(0.8)	2
Europe		0.1878	0.32 (0.05, 1.93)	0.31 (0.05, 1.93)	-2.8 (-7.8, 2.14)	3	(4.2)	3	2	(1.4)	2
Rest of World		0.1675	0.00 (not est.)	0.00 (not est.)	-1.8 (-5.4, 1.74)	1	(1.9)	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. TE SAE: Treatment emergent serious adverse events

Table 1.6.713.3.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.3829	0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1	(0.8)	1	6	(2.4)	8
Europe		0.5186	2.02 (0.23, 17.8)	2.06 (0.22, 19.1)	1.4 (-2.4, 5.15)	1	(1.4)	1	4	(2.7)	4
Rest of World		0.3111			1.9 (-.72, 4.49)	0	(0.0)	0	2	(1.9)	4
General disorders and administration site conditions											
Any											
Total	1.0000	0.3123			0.8 (-.30, 1.91)	0	(0.0)	0	2	(0.8)	2
Hernia											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	1
Injection site reaction											
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0	(0.0)	0	1	(0.4)	1
Infections and infestations											
Any											
Total	1.0000	0.2229			1.2 (-.15, 2.52)	0	(0.0)	0	3	(1.2)	3
Conjunctivitis											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	1
Otitis media											
Total	Not est.	0.4954			0.4 (-.38, 1.14)	0	(0.0)	0	1	(0.4)	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. TE SAE: Treatment emergent serious adverse events

Table 1.6.713.3.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Influenza									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Musculoskeletal and connective tissue disorders									
Any									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Myalgia									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Psychiatric disorders									
Any									
Total	1.0000	0.3123			0.8 (-.30, 1.91)	0 (0.0)	0	2 (0.8)	2
Anxiety									
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0 (0.0)	0	1 (0.4)	1
Mood altered									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Dermatitis atopic									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.6.714.3.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.6252	0.0185	2.40 (1.10, 5.22)	2.71 (1.15, 6.37)	7.8 (2.10, 13.5)	7	(5.6)	7	34	(13.5)	39
Europe		0.0182	2.54 (1.11, 5.83)	2.95 (1.17, 7.46)	12.8 (3.62, 22.0)	6	(8.3)	6	31	(21.1)	36
Rest of World		0.6933	1.56 (0.16, 14.7)	1.56 (0.16, 14.7)	1.0 (-3.8, 5.92)	1	(1.9)	1	3	(2.9)	3
Eye disorders											
Any											
Total	Not est.	0.6213	1.48 (0.31, 7.12)	1.50 (0.30, 7.61)	0.8 (-2.1, 3.64)	2	(1.6)	2	6	(2.4)	7
Keratitis											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	1
Conjunctivitis allergic											
Total	Not est.	0.8018	1.23 (0.25, 6.16)	1.24 (0.23, 6.53)	0.4 (-2.4, 3.13)	2	(1.6)	2	5	(2.0)	6
Infections and infestations											
Any											
Total	0.5509	0.0205	2.77 (1.10, 7.00)	3.04 (1.14, 8.11)	7.0 (1.91, 12.1)	5	(4.0)	5	28	(11.1)	32
Europe		0.0195	3.07 (1.10, 8.56)	3.48 (1.16, 10.4)	11.4 (3.39, 19.5)	4	(5.6)	4	25	(17.0)	29
Rest of World		0.6933	1.56 (0.16, 14.7)	1.56 (0.16, 14.7)	1.0 (-3.8, 5.92)	1	(1.9)	1	3	(2.9)	3
Conjunctivitis viral											
Total	Not est.	0.1605	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1	(0.8)	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

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Table 1.6.714.3.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Conjunctivitis											
Total	0.3724	0.0087	3.46 (1.25, 9.58)	3.95 (1.33, 11.7)	7.8 (2.97, 12.7)	4	(3.2)	4	28	(11.1)	32
Europe		0.0195	3.07 (1.10, 8.56)	3.48 (1.16, 10.4)	11.4 (3.39, 19.5)	4	(5.6)	4	25	(17.0)	29
Rest of World		0.2018			2.9 (-.31, 6.10)	0	(0.0)	0	3	(2.9)	3

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 1.6.715.3.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Europe					72	21.5		147	44.1	
Rest of World					54	16.4		105	30.9	

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 1.6.716.3.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Europe						72 21.5		147 44.1	
Rest of World						54 16.4		105 30.9	
Any system organ class									
Any preferred term									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	1
Europe		0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.7 (-3.8, 2.34)	1 (1.4)	1	1 (0.7)	1
Infections and infestations									
Any									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	1
Eczema herpeticum									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	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 1.6.717.3.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Europe					72	21.5		147	44.1	
Rest of World					54	16.4		105	30.9	

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 1.6.718.3.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Europe					72	21.5		147	44.1	
Rest of World					54	16.4		105	30.9	

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 1.6.719.3.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Europe					72	21.5		147	44.1	
Rest of World					54	16.4		105	30.9	

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 1.6.720.3.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Europe						72 21.5		147 44.1	
Rest of World						54 16.4		105 30.9	
Any system organ class									
Any preferred term									
Total	0.4747	0.0327	0.29 (0.09, 0.97)	0.27 (0.08, 0.96)	-3.9 (-8.2, 0.34)	7 (5.6)	9	4 (1.6)	4
Europe		0.4622	0.49 (0.07, 3.40)	0.48 (0.07, 3.49)	-1.4 (-5.7, 2.81)	2 (2.8)	4	2 (1.4)	2
Rest of World		0.0337	0.21 (0.04, 1.03)	0.19 (0.04, 1.01)	-7.3 (-15, 0.82)	5 (9.3)	5	2 (1.9)	2
Infections and infestations									
Any									
Total	0.4747	0.0327	0.29 (0.09, 0.97)	0.27 (0.08, 0.96)	-3.9 (-8.2, 0.34)	7 (5.6)	9	4 (1.6)	4
Europe		0.4622	0.49 (0.07, 3.40)	0.48 (0.07, 3.49)	-1.4 (-5.7, 2.81)	2 (2.8)	4	2 (1.4)	2
Rest of World		0.0337	0.21 (0.04, 1.03)	0.19 (0.04, 1.01)	-7.3 (-15, 0.82)	5 (9.3)	5	2 (1.9)	2
Infected dermal cyst									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Paronychia									
Total	Not est.	0.1675	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Cellulitis									
Total	0.3137	0.9983	1.00 (0.09, 11.2)	1.00 (0.09, 11.1)	-0.0 (-1.9, 1.90)	1 (0.8)	1	2 (0.8)	2
Impetigo									
Total	Not est.	0.6369	0.52 (0.03, 8.40)	0.52 (0.03, 8.30)	-0.4 (-2.1, 1.35)	1 (0.8)	1	1 (0.4)	1
Dermatitis infected									
Total	1.0000	0.0048	0.00 (not est.)	0.00 (not est.)	-3.2 (-6.2, -.11)	4 (3.2)	6	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

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Table 1.6.720.3.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Europe		0.0430	0.00 (not est.)	0.00 (not est.)	-2.8 (-6.6, 1.02)	2 (2.8)	4	0 (0.0)	0
Rest of World		0.0490	0.00 (not est.)	0.00 (not est.)	-3.7 (-8.7, 1.34)	2 (3.7)	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. TEAESI: Treatment emergent adverse events of special interest

Table 1.6.721.3.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Europe						72 21.5		147 44.1	
Rest of World						54 16.4		105 30.9	
Any system organ class									
Any preferred term									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Europe		0.1627	0.00 (not est.)	0.00 (not est.)	-1.4 (-4.1, 1.32)	1 (1.4)	1	0 (0.0)	0
Infections and infestations									
Any									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Dermatitis infected									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	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. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.6.722.3.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.9312	0.1972	1.10 (0.95, 1.27)	1.37 (0.85, 2.22)	6.2 (-3.3, 15.8)	81	(64.3)	168	178	(70.6)	494
Europe		0.4046	1.06 (0.92, 1.23)	1.34 (0.67, 2.67)	4.8 (-6.8, 16.4)	55	(76.4)	125	119	(81.0)	344
Rest of World		0.3238	1.17 (0.85, 1.61)	1.40 (0.72, 2.74)	8.2 (-7.9, 24.3)	26	(48.1)	43	59	(56.2)	150

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 1.6.723.3.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Europe						72	21.5		147	44.1	
Rest of World						54	16.4		105	30.9	
Any system organ class											
Any preferred term											
Total	0.3527	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4	(3.2)	4	2	(0.8)	2
Europe		0.1878	0.32 (0.05, 1.93)	0.31 (0.05, 1.93)	-2.8 (-7.8, 2.14)	3	(4.2)	3	2	(1.4)	2
Rest of World		0.1675	0.00 (not est.)	0.00 (not est.)	-1.8 (-5.4, 1.74)	1	(1.9)	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. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.7.101.3.1.1: Total, Moderate [IGA=3], Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	66	136
Age (years)		
Mean (sd)	37.7 (14.3)	39.6 (15.5)
Gender		
Female	30 (45.5%)	72 (52.9%)
Male	36 (54.5%)	64 (47.1%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	28.0 (6.0)	27.8 (6.3)
Race		
Asian	13 (19.7%)	8 (5.9%)
Black	5 (7.6%)	13 (9.6%)
White	45 (68.2%)	109 (80.1%)
Other	3 (4.5%)	6 (4.4%)
Geographic region		
Europe	33 (50.0%)	71 (52.2%)
USA	33 (50.0%)	65 (47.8%)
Body surface area (BSA) with AD (%)		
Mean (sd)	34.7 (19.6)	37.9 (18.5)
Duration of AD (years)		
Mean (sd)	28.5 (15.1)	26.4 (16.5)
Eczema Area and Severity Index (EASI)		
Mean (sd)	22.9 (6.8)	22.9 (7.8)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	66 (100%)	136 (100%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.7 (1.5)	7.3 (1.6)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.8 (2.2)	6.7 (2.2)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	62.4 (9.8)	59.8 (9.8)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	16.1 (7.3)	16.2 (7.1)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	10.6 (7.3)	11.0 (7.6)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	66.0 (20.7)	64.4 (24.3)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.648 (0.25)	0.597 (0.27)
Patients that have tried systemic corticosteroids (%)		
No	23 (34.8%)	70 (51.5%)
Yes	43 (65.2%)	66 (48.5%)
Previous number of treatments with systemic immunosuppressants*		
0	35 (53.0%)	95 (69.9%)
1	19 (28.8%)	32 (23.5%)
2	8 (12.1%)	6 (4.4%)
3	2 (3.0%)	2 (1.5%)
4	1 (1.5%)	
5	1 (1.5%)	1 (0.7%)

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.7.101.3.2.1: Total, Severe [IGA=4], Baseline characteristics of interest, LP0162-1339

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	60	116
Age (years)		
Mean (sd)	37.9 (15.5)	39.9 (15.2)
Gender		
Female	13 (21.7%)	55 (47.4%)
Male	47 (78.3%)	61 (52.6%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	25.9 (4.9)	27.4 (7.1)
Race		
Asian	11 (18.3%)	9 (7.8%)
Black	7 (11.7%)	9 (7.8%)
White	39 (65.0%)	94 (81.0%)
Other	3 (5.0%)	4 (3.4%)
Geographic region		
Europe	39 (65.0%)	76 (65.5%)
USA	21 (35.0%)	40 (34.5%)
Body surface area (BSA) with AD (%)		
Mean (sd)	64.5 (22.9)	58.9 (23.3)
Duration of AD (years)		
Mean (sd)	28.9 (15.2)	29.8 (16.2)
Eczema Area and Severity Index (EASI)		
Mean (sd)	38.7 (12.8)	35.8 (12.2)
Investigator's Global Assessment (IGA)		
Severe [IGA=4]	60 (100%)	116 (100%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	8.1 (1.4)	8.1 (1.2)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.4 (2.1)	7.2 (2.0)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	75.9 (12.8)	75.3 (11.8)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	18.4 (6.9)	19.2 (6.7)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	13.2 (7.8)	12.5 (7.0)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	52.3 (23.6)	52.9 (24.5)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.524 (0.30)	0.519 (0.29)
Patients that have tried systemic corticosteroids (%)		
No	18 (30.0%)	35 (30.2%)
Yes	42 (70.0%)	81 (69.8%)
Previous number of treatments with systemic immunosuppressants*		
0	27 (45.0%)	64 (55.2%)
1	20 (33.3%)	32 (27.6%)
2	10 (16.7%)	13 (11.2%)
3	3 (5.0%)	3 (2.6%)
4		4 (3.4%)

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.7.101.4.1.1: Total, Moderate [IGA=3], Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	70	68
Age (years)		
Mean (sd)	34.2 (13.5)	35.9 (13.5)
Gender		
Female	24 (34.3%)	27 (39.7%)
Male	46 (65.7%)	41 (60.3%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	25.2 (6.2)	25.4 (4.3)
Race		
White	70 (100%)	66 (97.1%)
Other		2 (2.9%)
Geographic region		
Europe	70 (100%)	68 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	44.0 (17.4)	46.3 (19.0)
Duration of AD (years)		
Mean (sd)	22.4 (12.0)	25.8 (12.5)
Eczema Area and Severity Index (EASI)		
Mean (sd)	27.1 (7.3)	26.0 (6.0)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	70 (100%)	68 (100%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.4 (1.4)	6.9 (1.4)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.7 (1.6)	6.0 (2.0)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	64.0 (9.9)	64.0 (8.4)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	15.0 (6.7)	15.2 (5.9)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	11.2 (7.2)	10.8 (6.4)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	55.4 (21.5)	58.6 (17.7)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.627 (0.22)	0.659 (0.20)
Patients that have tried systemic corticosteroids (%)		
No	30 (42.9%)	23 (33.8%)
Yes	40 (57.1%)	45 (66.2%)
Previous number of treatments with systemic immunosuppressants*		
0	14 (20.0%)	12 (17.6%)
1	40 (57.1%)	41 (60.3%)
2	12 (17.1%)	11 (16.2%)
3	3 (4.3%)	4 (5.9%)
5	1 (1.4%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.7.101.4.2.1: Total, Severe [IGA=4], Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	67	70
Age (years)		
Mean (sd)	38.1 (13.7)	37.7 (15.7)
Gender		
Female	30 (44.8%)	30 (42.9%)
Male	37 (55.2%)	40 (57.1%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	26.4 (5.2)	24.9 (4.2)
Race		
Asian	1 (1.5%)	
Black	1 (1.5%)	
White	65 (97.0%)	69 (98.6%)
Other		1 (1.4%)
Geographic region		
Europe	67 (100%)	70 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	66.9 (22.1)	61.7 (21.9)
Duration of AD (years)		
Mean (sd)	28.4 (15.6)	28.3 (15.0)
Eczema Area and Severity Index (EASI)		
Mean (sd)	40.9 (14.8)	38.0 (12.6)
Investigator's Global Assessment (IGA)		
Severe [IGA=4]	67 (100%)	70 (100%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.6 (1.4)	7.6 (1.4)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.1 (1.7)	6.6 (2.2)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	77.9 (11.7)	76.2 (12.0)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	17.8 (5.7)	16.5 (7.1)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	12.3 (7.8)	10.6 (6.5)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	49.5 (22.2)	54.6 (21.8)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.555 (0.26)	0.609 (0.24)
Patients that have tried systemic corticosteroids (%)		
No	16 (23.9%)	18 (25.7%)
Yes	51 (76.1%)	52 (74.3%)
Previous number of treatments with systemic immunosuppressants*		
0	9 (13.4%)	10 (14.3%)
1	38 (56.7%)	44 (62.9%)
2	15 (22.4%)	11 (15.7%)
3	3 (4.5%)	4 (5.7%)
4	2 (3.0%)	1 (1.4%)

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.7.102.3.1: Total, Moderate [IGA=3], Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Moderate [IGA=3]				
Analysis set				
N	66		136	
Blood and lymphatic system disorders				
Anaemia			5	(3.7)
Eosinophilia			1	(0.7)
Hypercoagulation			1	(0.7)
Cardiac disorders				
Ventricular extrasystoles	1	(1.5)		
Atrial fibrillation			2	(1.5)
Cardiac failure chronic			2	(1.5)
Angina pectoris			1	(0.7)
Arrhythmia			1	(0.7)
Bradycardia			1	(0.7)
Bundle branch block left			1	(0.7)
Bundle branch block right			1	(0.7)
Myocardial infarction			1	(0.7)
Congenital, familial and genetic disorders				
Atrial septal defect	2	(3.0)		
Congenital naevus	1	(1.5)		
Gilbert's syndrome	1	(1.5)		
Ichthyosis	1	(1.5)	1	(0.7)
Deafness congenital			1	(0.7)
Tourette's disorder			1	(0.7)
Type V hyperlipidaemia			1	(0.7)
Ear and labyrinth disorders				
Deafness bilateral	1	(1.5)	1	(0.7)
Hyperacusis	1	(1.5)		
Vertigo positional	1	(1.5)		
Deafness			1	(0.7)
Vertigo			1	(0.7)
Endocrine disorders				
Hypothyroidism	3	(4.5)	8	(5.9)
Autoimmune thyroiditis			1	(0.7)
Basedow's disease			1	(0.7)
Hyperthyroidism			1	(0.7)
Thyroid mass			1	(0.7)
Eye disorders				
Conjunctivitis allergic	14	(21.2)	25	(18.4)
Atopic keratoconjunctivitis	2	(3.0)	2	(1.5)
Blepharitis	1	(1.5)	1	(0.7)
Blindness unilateral	1	(1.5)		
Cataract	1	(1.5)	1	(0.7)
Keratitis	1	(1.5)		
Visual impairment	1	(1.5)		
Allergic keratitis			1	(0.7)
Ectropion			1	(0.7)
Eczema eyelids			1	(0.7)
Eye pruritus			1	(0.7)
Eyelid oedema			1	(0.7)
Keratoconus			1	(0.7)
Myopia			1	(0.7)
Presbyopia			1	(0.7)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	3	(4.5)	14	(10.3)
Dyspepsia	2	(3.0)	5	(3.7)
Haemorrhoids			3	(2.2)
Colitis ulcerative	1	(1.5)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.102.3.1: Total, Moderate [IGA=3], Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Moderate [IGA=3]				
Gastrointestinal disorders				
Colitis ulcerative			1	(0.7)
Diarrhoea	1	(1.5)		
Dysphagia	1	(1.5)		
Gastritis	1	(1.5)	1	(0.7)
Hiatus hernia	1	(1.5)		
Irritable bowel syndrome	1	(1.5)	2	(1.5)
Constipation			2	(1.5)
Abdominal distension			1	(0.7)
Crohn's disease			1	(0.7)
Diverticulum			1	(0.7)
Large intestine polyp			1	(0.7)
Nausea			1	(0.7)
Stress ulcer			1	(0.7)
Tooth malformation			1	(0.7)
General disorders and administration site conditions				
Asthenia			1	(0.7)
Drug intolerance			1	(0.7)
Gait disturbance			1	(0.7)
Pain			1	(0.7)
Hepatobiliary disorders				
Hyperbilirubinaemia	1	(1.5)		
Cholelithiasis			1	(0.7)
Immune system disorders				
Seasonal allergy	26	(39.4)	59	(43.4)
Food allergy	16	(24.2)	37	(27.2)
Drug hypersensitivity	7	(10.6)	9	(6.6)
Allergy to animal	3	(4.5)	9	(6.6)
Hypersensitivity	4	(6.1)	9	(6.6)
Rubber sensitivity	3	(4.5)	5	(3.7)
Dust allergy			6	(4.4)
Multiple allergies	1	(1.5)	6	(4.4)
Mite allergy	2	(3.0)	3	(2.2)
Sensitisation	2	(3.0)		
Allergy to chemicals			3	(2.2)
Allergy to metals	1	(1.5)	3	(2.2)
Milk allergy	1	(1.5)	3	(2.2)
Perfume sensitivity	1	(1.5)		
Allergy to plants			2	(1.5)
Allergy to arthropod sting			1	(0.7)
Iodine allergy			1	(0.7)
Infections and infestations				
Herpes simplex	2	(3.0)	3	(2.2)
Oral herpes	2	(3.0)	4	(2.9)
Chronic sinusitis	1	(1.5)	1	(0.7)
Hordeolum	1	(1.5)		
Rhinitis			2	(1.5)
Folliculitis			1	(0.7)
Paronychia			1	(0.7)
Sinusitis			1	(0.7)
Urinary tract infection			1	(0.7)
Injury, poisoning and procedural complications				
Ligament rupture	1	(1.5)		
Foot fracture			1	(0.7)
Limb injury			1	(0.7)
Tendon injury			1	(0.7)
Tendon rupture			1	(0.7)
Ulnar nerve injury			1	(0.7)
Investigations				
Alanine aminotransferase increased	1	(1.5)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.102.3.1: Total, Moderate [IGA=3], Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Moderate [IGA=3]				
Investigations				
Blood bilirubin increased	1	(1.5)		
Gamma-glutamyltransferase increased	1	(1.5)		
Blood cholesterol increased			2	(1.5)
Human papilloma virus test positive			1	(0.7)
Vitamin D decreased			1	(0.7)
Metabolism and nutrition disorders				
Type 2 diabetes mellitus	2	(3.0)	9	(6.6)
Obesity	3	(4.5)	8	(5.9)
Hyperlipidaemia	2	(3.0)	7	(5.1)
Hypercholesterolaemia	2	(3.0)	6	(4.4)
Hypertriglyceridaemia	1	(1.5)	5	(3.7)
Lactose intolerance	1	(1.5)	3	(2.2)
Decreased appetite	1	(1.5)		
Dyslipidaemia	1	(1.5)		
Folate deficiency	1	(1.5)		
Gout	1	(1.5)	2	(1.5)
Diabetes mellitus			1	(0.7)
Fructose intolerance			1	(0.7)
Glucose tolerance impaired			1	(0.7)
Gluten sensitivity			1	(0.7)
Hyperuricaemia			1	(0.7)
Hypoglycaemia			1	(0.7)
Iodine deficiency			1	(0.7)
Overweight			1	(0.7)
Vitamin D deficiency			1	(0.7)
Musculoskeletal and connective tissue disorders				
Osteoarthritis	3	(4.5)	9	(6.6)
Back pain	2	(3.0)	7	(5.1)
Arthralgia	1	(1.5)	4	(2.9)
Fibromyalgia	1	(1.5)		
Intervertebral disc degeneration	1	(1.5)	1	(0.7)
Neck pain	1	(1.5)	1	(0.7)
Pain in extremity	1	(1.5)		
Plantar fasciitis	1	(1.5)		
Psoriatic arthropathy	1	(1.5)		
Rotator cuff syndrome	1	(1.5)		
Intervertebral disc protrusion			2	(1.5)
Scoliosis			2	(1.5)
Ankylosing spondylitis			1	(0.7)
Arthritis			1	(0.7)
Haemarthrosis			1	(0.7)
Intervertebral disc disorder			1	(0.7)
Limb asymmetry			1	(0.7)
Muscle spasms			1	(0.7)
Muscular weakness			1	(0.7)
Neuropathic arthropathy			1	(0.7)
Osteonecrosis			1	(0.7)
Osteoporosis			1	(0.7)
Rheumatoid arthritis			1	(0.7)
Vertebral osteophyte			1	(0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Haemangioma	1	(1.5)	1	(0.7)
Seborrhoeic keratosis			2	(1.5)
Lipoma			1	(0.7)
Uterine leiomyoma			1	(0.7)
Nervous system disorders				
Headache	1	(1.5)	7	(5.1)
Migraine	3	(4.5)	4	(2.9)
Cervical radiculopathy	1	(1.5)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.102.3.1: Total, Moderate [IGA=3], Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Moderate [IGA=3]		
Nervous system disorders		
Tension headache	1 (1.5)	
Diabetic neuropathy		2 (1.5)
Carpal tunnel syndrome		1 (0.7)
Delayed sleep phase		1 (0.7)
Dizziness		1 (0.7)
Lumbar radiculopathy		1 (0.7)
Migraine with aura		1 (0.7)
Seizure		1 (0.7)
Somnolence		1 (0.7)
Psychiatric disorders		
Depression	3 (4.5)	13 (9.6)
Anxiety	4 (6.1)	11 (8.1)
Anxiety disorder	3 (4.5)	
Insomnia	2 (3.0)	5 (3.7)
Attention deficit/hyperactivity disorder	1 (1.5)	3 (2.2)
Autism spectrum disorder	1 (1.5)	
Body dysmorphic disorder	1 (1.5)	
Depersonalisation/derealisation disorder	1 (1.5)	
Generalised anxiety disorder	1 (1.5)	
Bulimia nervosa		1 (0.7)
Oppositional defiant disorder		1 (0.7)
Renal and urinary disorders		
Chronic kidney disease	1 (1.5)	
Pollakiuria	1 (1.5)	
Automatic bladder		1 (0.7)
Haematuria		1 (0.7)
Renal cyst		1 (0.7)
Renal failure		1 (0.7)
Reproductive system and breast disorders		
Cervical dysplasia	1 (1.5)	
Erectile dysfunction	1 (1.5)	
Pelvic congestion	1 (1.5)	
Benign prostatic hyperplasia		1 (0.7)
Dysmenorrhoea		1 (0.7)
Respiratory, thoracic and mediastinal disorders		
Asthma	27 (40.9)	59 (43.4)
Rhinitis allergic	7 (10.6)	17 (12.5)
Chronic obstructive pulmonary disease	3 (4.5)	5 (3.7)
Sleep apnoea syndrome		4 (2.9)
Nasal polyps	1 (1.5)	
Rhinitis perennial	1 (1.5)	
Adenoidal hypertrophy		1 (0.7)
Dyspnoea		1 (0.7)
Lung cyst		1 (0.7)
Vocal cord dysfunction		1 (0.7)
Skin and subcutaneous tissue disorders		
Acne		5 (3.7)
Androgenetic alopecia	2 (3.0)	1 (0.7)
Dermatitis contact	1 (1.5)	3 (2.2)
Alopecia	1 (1.5)	1 (0.7)
Alopecia universalis	1 (1.5)	
Chronic spontaneous urticaria	1 (1.5)	1 (0.7)
Dermal cyst	1 (1.5)	
Dermatitis papillaris capillitii	1 (1.5)	
Dyshidrotic eczema	1 (1.5)	
Hyperkeratosis	1 (1.5)	
Pruritus	1 (1.5)	
Psoriasis	1 (1.5)	

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.102.3.1: Total, Moderate [IGA=3], Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Moderate [IGA=3]				
Skin and subcutaneous tissue disorders				
Transient acantholytic dermatosis	1	(1.5)		
Urticaria	1	(1.5)	1	(0.7)
Vitiligo	1	(1.5)	2	(1.5)
Alopecia areata			2	(1.5)
Acanthosis nigricans			1	(0.7)
Actinic keratosis			1	(0.7)
Dry skin			1	(0.7)
Hidradenitis			1	(0.7)
Neurodermatitis			1	(0.7)
Rosacea			1	(0.7)
Social circumstances				
Tobacco user	4	(6.1)	3	(2.2)
Postmenopause	1	(1.5)	1	(0.7)
Surgical and medical procedures				
Alcohol rehabilitation	1	(1.5)		
Appendicectomy	1	(1.5)		
Caesarean section	1	(1.5)		
Immune tolerance induction	1	(1.5)		
Osteosynthesis	1	(1.5)		
Continuous positive airway pressure			1	(0.7)
Hip arthroplasty			1	(0.7)
Intra-uterine contraceptive device insertion			1	(0.7)
Knee arthroplasty			1	(0.7)
Vascular disorders				
Hypertension	10	(15.2)	22	(16.2)
Peripheral vascular disorder			3	(2.2)
Lymphoedema	1	(1.5)		
Arteriosclerosis			1	(0.7)
Deep vein thrombosis			1	(0.7)
Poor peripheral circulation			1	(0.7)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.102.3.1: Total, Severe [IGA=4], Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
Analysis set				
N	60		116	
Blood and lymphatic system disorders				
Lymphadenopathy	2	(3.3)		
Anaemia			2	(1.7)
Dermatopathic lymphadenopathy			1	(0.9)
Hypereosinophilic syndrome			1	(0.9)
Iron deficiency anaemia			1	(0.9)
Leukocytosis			1	(0.9)
Lymphadenitis			1	(0.9)
Cardiac disorders				
Bundle branch block right	1	(1.7)	2	(1.7)
Atrioventricular block first degree	1	(1.7)		
Congenital, familial and genetic disorders				
Gilbert's syndrome	1	(1.7)		
Ichthyosis	1	(1.7)		
Multiple lentigines syndrome	1	(1.7)		
Thalassaemia beta	1	(1.7)		
Arrhythmogenic right ventricular dysplasia			1	(0.9)
Sickle cell trait			1	(0.9)
Type V hyperlipidaemia			1	(0.9)
Ear and labyrinth disorders				
Deafness unilateral	1	(1.7)		
Deafness			1	(0.9)
Deafness bilateral			1	(0.9)
Tinnitus			1	(0.9)
Vertigo			1	(0.9)
Endocrine disorders				
Hypothyroidism	1	(1.7)	3	(2.6)
Autoimmune thyroiditis			1	(0.9)
Eye disorders				
Conjunctivitis allergic	12	(20.0)	29	(25.0)
Atopic keratoconjunctivitis	2	(3.3)	5	(4.3)
Dry eye			3	(2.6)
Cataract			2	(1.7)
Glaucoma			2	(1.7)
Myopia			2	(1.7)
Keratoconus	1	(1.7)		
Astigmatism			1	(0.9)
Blindness			1	(0.9)
Blindness day			1	(0.9)
Blindness unilateral			1	(0.9)
Corneal opacity			1	(0.9)
Presbyopia			1	(0.9)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	2	(3.3)	5	(4.3)
Cheilitis	1	(1.7)		
Chronic gastritis	1	(1.7)		
Constipation	1	(1.7)	1	(0.9)
Dyspepsia	1	(1.7)		
Gastritis	1	(1.7)		
Pancreatic cyst	1	(1.7)		
Irritable bowel syndrome			1	(0.9)
Oesophagitis			1	(0.9)
General disorders and administration site conditions				
Fatigue	1	(1.7)		

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Table 1.7.102.3.1: Total, Severe [IGA=4], Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
General disorders and administration site conditions				
Drug chemical incompatibility			1	(0.9)
Drug intolerance			1	(0.9)
Hernia			1	(0.9)
Pain			1	(0.9)
Peripheral swelling			1	(0.9)
Immune system disorders				
Seasonal allergy	30	(50.0)	62	(53.4)
Food allergy	28	(46.7)	46	(39.7)
Drug hypersensitivity	4	(6.7)	13	(11.2)
Hypersensitivity	3	(5.0)	8	(6.9)
Multiple allergies	2	(3.3)	7	(6.0)
Allergy to animal	3	(5.0)	4	(3.4)
Mite allergy	2	(3.3)	2	(1.7)
Dust allergy			2	(1.7)
Allergy to chemicals	1	(1.7)	1	(0.9)
Allergy to metals	1	(1.7)		
Rubber sensitivity	1	(1.7)		
Allergy to arthropod sting			1	(0.9)
Mycotic allergy			1	(0.9)
Reaction to colouring			1	(0.9)
Infections and infestations				
Herpes simplex	5	(8.3)	5	(4.3)
Rhinitis	2	(3.3)	2	(1.7)
Conjunctivitis	1	(1.7)	2	(1.7)
Oral herpes	1	(1.7)	2	(1.7)
Eczema herpeticum	1	(1.7)	1	(0.9)
Conjunctivitis bacterial			1	(0.9)
Onychomycosis			1	(0.9)
Tinea versicolour			1	(0.9)
Viral upper respiratory tract infection			1	(0.9)
Injury, poisoning and procedural complications				
Joint injury			2	(1.7)
Muscle strain	1	(1.7)		
Ligament sprain			1	(0.9)
Meniscus injury			1	(0.9)
Tibia fracture			1	(0.9)
Investigations				
Blood cholesterol increased	3	(5.0)		
Blood immunoglobulin E increased	1	(1.7)	2	(1.7)
Basophil count decreased	1	(1.7)		
Blood lactate dehydrogenase increased	1	(1.7)		
Blood pressure increased	1	(1.7)		
Blood triglycerides increased	1	(1.7)		
Cardiac murmur	1	(1.7)		
Electrocardiogram QT shortened	1	(1.7)		
Low density lipoprotein increased	1	(1.7)	1	(0.9)
Mean cell volume decreased	1	(1.7)		
Alanine aminotransferase increased			1	(0.9)
Eosinophil count increased			1	(0.9)
Gamma-glutamyltransferase increased			1	(0.9)
Hepatic enzyme increased			1	(0.9)
Human papilloma virus test			1	(0.9)
Metabolism and nutrition disorders				
Obesity	1	(1.7)	6	(5.2)
Hypercholesterolaemia			5	(4.3)
Gout	2	(3.3)	2	(1.7)
Type 2 diabetes mellitus	2	(3.3)	2	(1.7)
Vitamin D deficiency	2	(3.3)		

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Table 1.7.102.3.1: Total, Severe [IGA=4], Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
Metabolism and nutrition disorders				
Vitamin D deficiency			2	(1.7)
Lactose intolerance			3	(2.6)
Gluten sensitivity			2	(1.7)
Hyperlipidaemia			2	(1.7)
Diabetes mellitus	1	(1.7)	1	(0.9)
Haemochromatosis	1	(1.7)		
Cow's milk intolerance			1	(0.9)
Decreased appetite			1	(0.9)
Hyperuricaemia			1	(0.9)
Hypokalaemia			1	(0.9)
Vitamin B12 deficiency			1	(0.9)
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion			4	(3.4)
Back pain			3	(2.6)
Arthritis	1	(1.7)	2	(1.7)
Osteoarthritis			2	(1.7)
Ankylosing spondylitis	1	(1.7)		
Arthralgia	1	(1.7)	1	(0.9)
Joint instability	1	(1.7)		
Systemic lupus erythematosus	1	(1.7)		
Bursitis			1	(0.9)
Costochondritis			1	(0.9)
Joint swelling			1	(0.9)
Muscle spasms			1	(0.9)
Muscle tightness			1	(0.9)
Plantar fasciitis			1	(0.9)
Rheumatoid arthritis			1	(0.9)
Scoliosis			1	(0.9)
Temporomandibular joint syndrome			1	(0.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acoustic neuroma	1	(1.7)		
Skin papilloma	1	(1.7)		
Leiomyoma			1	(0.9)
Seborrhoeic keratosis			1	(0.9)
Nervous system disorders				
Headache	2	(3.3)	5	(4.3)
Migraine	1	(1.7)	3	(2.6)
Seizure	1	(1.7)		
Carpal tunnel syndrome			1	(0.9)
Epilepsy			1	(0.9)
Psychiatric disorders				
Depression			11	(9.5)
Insomnia	1	(1.7)	7	(6.0)
Anxiety	1	(1.7)	4	(3.4)
Autism spectrum disorder	2	(3.3)		
Attention deficit/hyperactivity disorder	1	(1.7)		
Sleep disorder	1	(1.7)	1	(0.9)
Stress	1	(1.7)		
Post-traumatic stress disorder			1	(0.9)
Social anxiety disorder			1	(0.9)
Renal and urinary disorders				
Renal cyst	2	(3.3)		
Renal colic	1	(1.7)		
Chronic kidney disease			1	(0.9)
Reproductive system and breast disorders				
Benign prostatic hyperplasia			1	(0.9)
Dysmenorrhoea			1	(0.9)
Erectile dysfunction			1	(0.9)

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Table 1.7.102.3.1: Total, Severe [IGA=4], Current medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Severe [IGA=4]		
Reproductive system and breast disorders		
Ovarian cyst		1 (0.9)
Respiratory, thoracic and mediastinal disorders		
Asthma	31 (51.7)	60 (51.7)
Rhinitis allergic	8 (13.3)	6 (5.2)
Sleep apnoea syndrome	1 (1.7)	3 (2.6)
Chronic obstructive pulmonary disease	1 (1.7)	2 (1.7)
Skin and subcutaneous tissue disorders		
Alopecia areata	3 (5.0)	2 (1.7)
Vitiligo	3 (5.0)	1 (0.9)
Alopecia	1 (1.7)	2 (1.7)
Androgenetic alopecia	1 (1.7)	2 (1.7)
Dermal cyst	1 (1.7)	1 (0.9)
Dermatitis contact	1 (1.7)	1 (0.9)
Neurodermatitis	1 (1.7)	
Pruritus	1 (1.7)	1 (0.9)
Acne		1 (0.9)
Actinic keratosis		1 (0.9)
Keratosis pilaris		1 (0.9)
Lichen sclerosus		1 (0.9)
Urticaria		1 (0.9)
Social circumstances		
Postmenopause	2 (3.3)	1 (0.9)
Tobacco user	1 (1.7)	2 (1.7)
Menopause		1 (0.9)
Surgical and medical procedures		
Heart valve replacement	1 (1.7)	1 (0.9)
Vasectomy	1 (1.7)	
Cataract operation		1 (0.9)
Corneal transplant		1 (0.9)
Intra-uterine contraceptive device		1 (0.9)
Keratoplasty		1 (0.9)
Vascular disorders		
Hypertension	10 (16.7)	21 (18.1)
Raynaud's phenomenon	1 (1.7)	

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Table 1.7.102.4.1: Total, Moderate [IGA=3], Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Moderate [IGA=3]				
Analysis set				
N	70		68	
Blood and lymphatic system disorders				
Iron deficiency anaemia			1	(1.5)
Cardiac disorders				
Sinus bradycardia	1	(1.4)	2	(2.9)
Atrial fibrillation	1	(1.4)	1	(1.5)
Atrioventricular block first degree			1	(1.5)
Bradycardia			1	(1.5)
Bundle branch block left			1	(1.5)
Atrial flutter	1	(1.4)		
Atrioventricular block	1	(1.4)		
Bundle branch block right	1	(1.4)		
Myocardial infarction	1	(1.4)		
Myocardial ischaemia	1	(1.4)		
Congenital, familial and genetic disorders				
Von Willebrand's disease			1	(1.5)
Congenital anomaly	1	(1.4)		
Cytogenetic abnormality	1	(1.4)		
Gilbert's syndrome	1	(1.4)		
Ear and labyrinth disorders				
Tinnitus	1	(1.4)		
Endocrine disorders				
Hypothyroidism	1	(1.4)	6	(8.8)
Hyperprolactinaemia			1	(1.5)
Autoimmune thyroiditis	1	(1.4)		
Eye disorders				
Conjunctivitis allergic	14	(20.0)	20	(29.4)
Atopic keratoconjunctivitis	2	(2.9)	1	(1.5)
Dry eye	2	(2.9)		
Keratoconus	2	(2.9)		
Glaucoma			1	(1.5)
Keratitis			1	(1.5)
Astigmatism	1	(1.4)		
Gastrointestinal disorders				
Chronic gastritis			1	(1.5)
Dyspepsia			1	(1.5)
Haemorrhoids			1	(1.5)
Hiatus hernia			1	(1.5)
Irritable bowel syndrome			1	(1.5)
General disorders and administration site conditions				
Xerosis	1	(1.4)	1	(1.5)
Hernia	1	(1.4)		
Hepatobiliary disorders				
Hepatic steatosis			1	(1.5)
Immune system disorders				
Seasonal allergy	31	(44.3)	36	(52.9)
Food allergy	22	(31.4)	24	(35.3)
Allergy to animal	9	(12.9)	4	(5.9)
Drug hypersensitivity	3	(4.3)	7	(10.3)
Mite allergy	5	(7.1)	6	(8.8)
Multiple allergies	3	(4.3)	5	(7.4)
Allergy to metals			3	(4.4)
Milk allergy	1	(1.4)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.102.4.1: Total, Moderate [IGA=3], Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Moderate [IGA=3]				
Immune system disorders				
Milk allergy			3	(4.4)
Allergy to plants	2	(2.9)	2	(2.9)
Hypersensitivity	2	(2.9)	2	(2.9)
Rubber sensitivity	1	(1.4)	2	(2.9)
Allergy to chemicals			1	(1.5)
Iodine allergy			1	(1.5)
Perfume sensitivity			1	(1.5)
Dust allergy	1	(1.4)		
Flour sensitivity	1	(1.4)		
Infections and infestations				
Herpes simplex	5	(7.1)	10	(14.7)
Epididymitis			1	(1.5)
Papilloma viral infection			1	(1.5)
Rhinitis			1	(1.5)
Sinusitis			1	(1.5)
Conjunctivitis	1	(1.4)		
Oral herpes	1	(1.4)		
Injury, poisoning and procedural complications				
Scar			2	(2.9)
Joint injury			1	(1.5)
Meniscus injury			1	(1.5)
Investigations				
Aspartate aminotransferase increased	1	(1.4)		
Gamma-glutamyltransferase increased	1	(1.4)		
Mean cell volume increased	1	(1.4)		
Metabolism and nutrition disorders				
Hypercholesterolaemia			3	(4.4)
Vitamin D deficiency	1	(1.4)	2	(2.9)
Gluten sensitivity	2	(2.9)		
Gout	2	(2.9)		
Lactose intolerance	2	(2.9)		
Hyperlipidaemia	1	(1.4)	1	(1.5)
Hypertriglyceridaemia			1	(1.5)
Dyslipidaemia	1	(1.4)		
Iron deficiency	1	(1.4)		
Type 2 diabetes mellitus	1	(1.4)		
Musculoskeletal and connective tissue disorders				
Back pain			3	(4.4)
Arthralgia	3	(4.3)		
Ankylosing spondylitis			1	(1.5)
Foot deformity			1	(1.5)
Intervertebral disc protrusion			1	(1.5)
Osteoarthritis			1	(1.5)
Growth retardation	1	(1.4)		
Myalgia	1	(1.4)		
Plica syndrome	1	(1.4)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Melanocytic naevus			2	(2.9)
Blepharal papilloma			1	(1.5)
Fibroma			1	(1.5)
Skin papilloma			1	(1.5)
Nervous system disorders				
Headache			5	(7.4)
Migraine	4	(5.7)	5	(7.4)
Dysaesthesia	1	(1.4)		
Epilepsy	1	(1.4)		

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Table 1.7.102.4.1: Total, Moderate [IGA=3], Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Moderate [IGA=3]		
Nervous system disorders		
Migraine with aura	1 (1.4)	
Restless legs syndrome	1 (1.4)	
Psychiatric disorders		
Depressed mood		2 (2.9)
Anxiety	1 (1.4)	1 (1.5)
Attention deficit/hyperactivity disorder		1 (1.5)
Depression	1 (1.4)	1 (1.5)
Stress		1 (1.5)
Eating disorder	1 (1.4)	
Nervousness	1 (1.4)	
Renal and urinary disorders		
Nephrolithiasis		1 (1.5)
Incontinence	1 (1.4)	
Proteinuria	1 (1.4)	
Reproductive system and breast disorders		
Dysmenorrhoea		1 (1.5)
Erectile dysfunction	1 (1.4)	
Menstrual disorder	1 (1.4)	
Polycystic ovaries	1 (1.4)	
Respiratory, thoracic and mediastinal disorders		
Asthma	36 (51.4)	26 (38.2)
Rhinitis allergic	10 (14.3)	5 (7.4)
Nasal septum deviation	1 (1.4)	2 (2.9)
Chronic obstructive pulmonary disease		1 (1.5)
Dysphonia		1 (1.5)
Nasal polyps	1 (1.4)	
Skin and subcutaneous tissue disorders		
Acne		1 (1.5)
Alopecia areata	1 (1.4)	1 (1.5)
Urticaria		1 (1.5)
Vitiligo	1 (1.4)	1 (1.5)
Alopecia	1 (1.4)	
Dermatitis contact	1 (1.4)	
Psoriasis	1 (1.4)	
Skin sensitisation	1 (1.4)	
Social circumstances		
Menopause		1 (1.5)
Surgical and medical procedures		
Cardiac pacemaker insertion		1 (1.5)
Knee operation		1 (1.5)
Maxillofacial operation	1 (1.4)	
Vascular disorders		
Hypertension	13 (18.6)	9 (13.2)
Peripheral venous disease		2 (2.9)
Spider vein		1 (1.5)
Varicose vein		1 (1.5)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.102.4.1: Total, Severe [IGA=4], Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
Analysis set				
N	67		70	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	1	(1.5)		
Thrombocytopenia	1	(1.5)		
Eosinophilia			1	(1.4)
Lymphadenopathy			1	(1.4)
Lymphopenia			1	(1.4)
Cardiac disorders				
Bundle branch block right	2	(3.0)		
Cardiomyopathy	1	(1.5)		
Atrial fibrillation			1	(1.4)
Congestive cardiomyopathy			1	(1.4)
Mitral valve incompetence			1	(1.4)
Tachycardia			1	(1.4)
Congenital, familial and genetic disorders				
Benign familial haematuria	1	(1.5)		
Congenital cystic kidney disease	1	(1.5)		
Sickle cell anaemia	1	(1.5)		
Ear and labyrinth disorders				
Deafness	1	(1.5)		
Deafness neurosensory	1	(1.5)		
Endocrine disorders				
Hypothyroidism	1	(1.5)	3	(4.3)
Autoimmune thyroiditis	2	(3.0)		
Thyroid mass	1	(1.5)		
Goitre			1	(1.4)
Thyroiditis			1	(1.4)
Eye disorders				
Conjunctivitis allergic	27	(40.3)	20	(28.6)
Atopic keratoconjunctivitis	7	(10.4)		
Cataract			3	(4.3)
Blepharitis			2	(2.9)
Myopia			2	(2.9)
Dry eye	1	(1.5)		
Glaucoma	1	(1.5)		
Keratoconus	1	(1.5)		
Photophobia			1	(1.4)
Retinal degeneration			1	(1.4)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	3	(4.5)	4	(5.7)
Chronic gastritis	2	(3.0)		
Hiatus hernia	2	(3.0)		
Irritable bowel syndrome	2	(3.0)		
Oesophagitis			2	(2.9)
Barrett's oesophagus	1	(1.5)	1	(1.4)
Coeliac disease	1	(1.5)	1	(1.4)
Crohn's disease	1	(1.5)		
Gastritis	1	(1.5)		
Haemorrhoids	1	(1.5)		
Colitis ulcerative			1	(1.4)
Dyspepsia			1	(1.4)
Gastric ulcer			1	(1.4)
General disorders and administration site conditions				
Xerosis			3	(4.3)
Dysplasia	1	(1.5)		

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Table 1.7.102.4.1: Total, Severe [IGA=4], Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
General disorders and administration site conditions				
Oedema peripheral	1	(1.5)		
Immune system disorders				
Seasonal allergy	39	(58.2)	40	(57.1)
Food allergy	28	(41.8)	26	(37.1)
Mite allergy	11	(16.4)	8	(11.4)
Allergy to animal	8	(11.9)	6	(8.6)
Drug hypersensitivity	6	(9.0)	5	(7.1)
Multiple allergies	6	(9.0)	6	(8.6)
Hypersensitivity	2	(3.0)	1	(1.4)
Allergy to chemicals	1	(1.5)	2	(2.9)
Allergy to metals	1	(1.5)	2	(2.9)
Allergy to plants	1	(1.5)	2	(2.9)
Dust allergy			2	(2.9)
Rubber sensitivity			2	(2.9)
Mycotic allergy	1	(1.5)	1	(1.4)
Oral allergy syndrome			1	(1.4)
Infections and infestations				
Herpes simplex	6	(9.0)	3	(4.3)
Sinusitis	2	(3.0)		
Oral herpes			2	(2.9)
Onychomycosis	1	(1.5)		
Ear infection			1	(1.4)
Rhinitis			1	(1.4)
Skin candida			1	(1.4)
Injury, poisoning and procedural complications				
Deafness traumatic	1	(1.5)		
Ligament sprain			1	(1.4)
Investigations				
Blood immunoglobulin E increased	1	(1.5)	1	(1.4)
Lymph node palpable	1	(1.5)		
Neutrophil count increased	1	(1.5)		
Vitamin B12 decreased	1	(1.5)		
White blood cell count increased	1	(1.5)		
Blood uric acid increased			1	(1.4)
Gamma-glutamyltransferase increased			1	(1.4)
Metabolism and nutrition disorders				
Diabetes mellitus			4	(5.7)
Hypercholesterolaemia	3	(4.5)	2	(2.9)
Dyslipidaemia	2	(3.0)	1	(1.4)
Obesity	2	(3.0)	2	(2.9)
Hyperuricaemia	1	(1.5)	2	(2.9)
Glucose tolerance impaired	1	(1.5)		
Gluten sensitivity	1	(1.5)		
Gout	1	(1.5)		
Hyperlipidaemia	1	(1.5)		
Lactose intolerance	1	(1.5)		
Mineral deficiency	1	(1.5)		
Vitamin D deficiency	1	(1.5)		
Histamine intolerance			1	(1.4)
Hyperinsulinism			1	(1.4)
Iron deficiency			1	(1.4)
Overweight			1	(1.4)
Purine metabolism disorder			1	(1.4)
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion	2	(3.0)	2	(2.9)
Osteoarthritis	2	(3.0)	2	(2.9)
Osteopenia	2	(3.0)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.102.4.1: Total, Severe [IGA=4], Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
Musculoskeletal and connective tissue disorders				
Back pain	1	(1.5)	2	(2.9)
Osteoporosis	1	(1.5)	2	(2.9)
Intervertebral disc disorder	1	(1.5)		
Joint range of motion decreased	1	(1.5)		
Myalgia	1	(1.5)		
Osteochondrosis	1	(1.5)		
Spinal osteoarthritis	1	(1.5)		
Temporomandibular joint syndrome	1	(1.5)		
Fibromyalgia			1	(1.4)
Lumbar spinal stenosis			1	(1.4)
Muscle spasms			1	(1.4)
Spinal pain			1	(1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Melanocytic naevus			2	(2.9)
Haemangioma	1	(1.5)		
Haemangioma of liver			1	(1.4)
Nervous system disorders				
Headache	5	(7.5)	2	(2.9)
Hypertonia			2	(2.9)
Hydrocephalus	1	(1.5)		
Migraine	1	(1.5)	1	(1.4)
Multiple sclerosis	1	(1.5)		
Narcolepsy	1	(1.5)		
Paralysis	1	(1.5)		
Restless legs syndrome	1	(1.5)		
Psychiatric disorders				
Anxiety			4	(5.7)
Depression	3	(4.5)	2	(2.9)
Insomnia	2	(3.0)	1	(1.4)
Depressed mood	1	(1.5)		
Fear of injection	1	(1.5)		
Sleep disorder	1	(1.5)	1	(1.4)
Affective disorder			1	(1.4)
Renal and urinary disorders				
Proteinuria	3	(4.5)		
Haematuria	2	(3.0)		
Renal cyst	1	(1.5)		
Renal disorder	1	(1.5)		
Renal failure	1	(1.5)	1	(1.4)
Renal vein compression	1	(1.5)		
Chronic kidney disease			1	(1.4)
IgA nephropathy			1	(1.4)
Nephrolithiasis			1	(1.4)
Reproductive system and breast disorders				
Benign prostatic hyperplasia	2	(3.0)	1	(1.4)
Dysmenorrhoea	1	(1.5)		
Premenstrual syndrome	1	(1.5)		
Gynaecomastia			1	(1.4)
Ovarian cyst			1	(1.4)
Testicular cyst			1	(1.4)
Respiratory, thoracic and mediastinal disorders				
Asthma	38	(56.7)	36	(51.4)
Rhinitis allergic	10	(14.9)	4	(5.7)
Bronchial hyperreactivity	1	(1.5)		
Nasal septum deviation	1	(1.5)		
Sinus disorder	1	(1.5)		
Bronchiectasis			1	(1.4)

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Table 1.7.102.4.1: Total, Severe [IGA=4], Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	(%)	Tralokinumab Q2W + TCS n	(%)
Severe [IGA=4]				
Respiratory, thoracic and mediastinal disorders				
Bronchitis chronic			1	(1.4)
Chronic obstructive pulmonary disease			1	(1.4)
Nasal turbinate hypertrophy			1	(1.4)
Sleep apnoea syndrome			1	(1.4)
Skin and subcutaneous tissue disorders				
Alopecia areata	2	(3.0)		
Alopecia	1	(1.5)		
Photosensitivity reaction	1	(1.5)	1	(1.4)
Urticaria	1	(1.5)		
Acne			1	(1.4)
Androgenetic alopecia			1	(1.4)
Dermatitis contact			1	(1.4)
Rosacea			1	(1.4)
Social circumstances				
Postmenopause	1	(1.5)		
Menopause			1	(1.4)
Surgical and medical procedures				
Female sterilisation	1	(1.5)		
Gastric bypass	1	(1.5)		
Lip lesion excision	1	(1.5)		
Nasal septal operation	1	(1.5)		
Sterilisation	1	(1.5)		
Thyroid nodule removal	1	(1.5)		
Thyroidectomy	1	(1.5)		
Cardiac resynchronisation therapy			1	(1.4)
Contraception			1	(1.4)
Intra-uterine contraceptive device			1	(1.4)
Vascular disorders				
Hypertension	12	(17.9)	14	(20.0)
Peripheral venous disease	2	(3.0)	1	(1.4)
Varicose vein	1	(1.5)		

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Table 1.7.103.3.1: Total, Moderate [IGA=3], Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Moderate [IGA=3]				
Analysis set				
N	66		136	
Blood and lymphatic system disorders				
Dermatopathic lymphadenopathy	1	(1.5)		
Iron deficiency anaemia	1	(1.5)		
Cardiac disorders				
Myocardial infarction			2	(1.5)
Congenital, familial and genetic disorders				
Cryptorchism	1	(1.5)		
Phimosis	1	(1.5)		
Ear and labyrinth disorders				
Ear disorder	1	(1.5)		
Eye disorders				
Atopic keratoconjunctivitis	1	(1.5)		
Cataract	1	(1.5)	2	(1.5)
Conjunctivitis allergic	1	(1.5)		
Blepharitis			1	(0.7)
Dry eye			1	(0.7)
Strabismus			1	(0.7)
Gastrointestinal disorders				
Inguinal hernia	2	(3.0)	2	(1.5)
Chronic gastritis	1	(1.5)		
Haemorrhoids	1	(1.5)	1	(0.7)
Abdominal hernia			1	(0.7)
Colitis			1	(0.7)
Gingival recession			1	(0.7)
Lumbar hernia			1	(0.7)
Oesophagitis			1	(0.7)
Rectal prolapse			1	(0.7)
Umbilical hernia			1	(0.7)
General disorders and administration site conditions				
Chest pain			1	(0.7)
Cyst			1	(0.7)
Fatigue			1	(0.7)
Hepatobiliary disorders				
Cholecystitis	1	(1.5)	2	(1.5)
Hepatic steatosis			1	(0.7)
Immune system disorders				
Food allergy	3	(4.5)	1	(0.7)
Seasonal allergy			3	(2.2)
Allergy to animal			1	(0.7)
Infections and infestations				
Eczema herpeticum	4	(6.1)	1	(0.7)
Impetigo	3	(4.5)	4	(2.9)
Erysipelas	2	(3.0)		
Appendicitis	1	(1.5)	3	(2.2)
Bronchitis	1	(1.5)		
Herpes zoster	1	(1.5)	1	(0.7)
Measles	1	(1.5)		
Molluscum contagiosum	1	(1.5)		
Oral herpes	1	(1.5)	1	(0.7)
Peritonsillitis	1	(1.5)		
Poliomyelitis	1	(1.5)		
Varicella	1	(1.5)		

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Table 1.7.103.3.1: Total, Moderate [IGA=3], Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Moderate [IGA=3]		
Infections and infestations		
Herpes simplex		2 (1.5)
Sinusitis		2 (1.5)
Staphylococcal infection		2 (1.5)
Tonsillitis		2 (1.5)
Abscess limb		1 (0.7)
Acarodermatitis		1 (0.7)
Acute sinusitis		1 (0.7)
Adenoiditis		1 (0.7)
Ascariasis		1 (0.7)
Cellulitis		1 (0.7)
Clostridium difficile colitis		1 (0.7)
Conjunctivitis		1 (0.7)
Conjunctivitis bacterial		1 (0.7)
External ear cellulitis		1 (0.7)
Furuncle		1 (0.7)
Kidney infection		1 (0.7)
Lyme disease		1 (0.7)
Neuroborreliosis		1 (0.7)
Oesophageal candidiasis		1 (0.7)
Papilloma viral infection		1 (0.7)
Tinea pedis		1 (0.7)
Viral upper respiratory tract infection		1 (0.7)
Vulvovaginal mycotic infection		1 (0.7)
Wound infection staphylococcal		1 (0.7)
Injury, poisoning and procedural complications		
Wrist fracture	2 (3.0)	
Cartilage injury	1 (1.5)	
Clavicle fracture	1 (1.5)	
Fall	1 (1.5)	
Hand fracture	1 (1.5)	
Ligament rupture	1 (1.5)	1 (0.7)
Arthropod bite		1 (0.7)
Femoral neck fracture		1 (0.7)
Injury		1 (0.7)
Investigations		
Arthroscopy	1 (1.5)	
Blood pressure increased	1 (1.5)	
Colonoscopy	1 (1.5)	2 (1.5)
Catheterisation cardiac		1 (0.7)
Endoscopy		1 (0.7)
Laparoscopy		1 (0.7)
Smear cervix		1 (0.7)
Metabolism and nutrition disorders		
Hypercholesterolaemia	1 (1.5)	1 (0.7)
Type 2 diabetes mellitus		1 (0.7)
Musculoskeletal and connective tissue disorders		
Arthralgia	1 (1.5)	1 (0.7)
Intervertebral disc protrusion	1 (1.5)	1 (0.7)
Juvenile idiopathic arthritis	1 (1.5)	
Limb mass	1 (1.5)	
Rotator cuff syndrome	1 (1.5)	
Exostosis		1 (0.7)
Osteochondrosis		1 (0.7)
Pain in extremity		1 (0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Haemangioma	2 (3.0)	
Basal cell carcinoma	1 (1.5)	1 (0.7)
Cervix carcinoma	1 (1.5)	

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Table 1.7.103.3.1: Total, Moderate [IGA=3], Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Moderate [IGA=3]		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Anogenital warts		1 (0.7)
Colon cancer		1 (0.7)
Dysplastic naevus		1 (0.7)
Osteochondroma		1 (0.7)
Skin papilloma		1 (0.7)
Nervous system disorders		
Cerebrovascular accident	1 (1.5)	
Trigeminal neuralgia	1 (1.5)	
Migraine		2 (1.5)
Alcoholic seizure		1 (0.7)
Facial paresis		1 (0.7)
Headache		1 (0.7)
Sciatica		1 (0.7)
Pregnancy, puerperium and perinatal conditions		
Abortion spontaneous		1 (0.7)
Ectopic pregnancy		1 (0.7)
Psychiatric disorders		
Depression	2 (3.0)	2 (1.5)
Alcohol problem		1 (0.7)
Anxiety		1 (0.7)
Renal and urinary disorders		
Nephrolithiasis		1 (0.7)
Reproductive system and breast disorders		
Menorrhagia	1 (1.5)	
Testicular retraction	1 (1.5)	
Cervical dysplasia		1 (0.7)
Dysmenorrhoea		1 (0.7)
Ovarian cyst		1 (0.7)
Ovarian cyst ruptured		1 (0.7)
Respiratory, thoracic and mediastinal disorders		
Asthma	5 (7.6)	4 (2.9)
Nasal septum deviation	1 (1.5)	
Dyspnoea		1 (0.7)
Skin and subcutaneous tissue disorders		
Urticaria	2 (3.0)	2 (1.5)
Acne	1 (1.5)	
Dermatitis contact		1 (0.7)
Dyshidrotic eczema		1 (0.7)
Papulopustular rosacea		1 (0.7)
Rosacea		1 (0.7)
Social circumstances		
Infant		1 (0.7)
Surgical and medical procedures		
Hysterectomy	4 (6.1)	4 (2.9)
Appendicectomy	3 (4.5)	8 (5.9)
Caesarean section		8 (5.9)
Cholecystectomy	1 (1.5)	8 (5.9)
Female sterilisation	3 (4.5)	3 (2.2)
Tonsillectomy	3 (4.5)	6 (4.4)
Wisdom teeth removal	3 (4.5)	2 (1.5)
Knee operation	2 (3.0)	3 (2.2)
Skin neoplasm excision	2 (3.0)	1 (0.7)
Salpingectomy		3 (2.2)
Circumcision	1 (1.5)	

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Table 1.7.103.3.1: Total, Moderate [IGA=3], Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Moderate [IGA=3]				
Surgical and medical procedures				
Endometrial ablation	1	(1.5)	1	(0.7)
Eye operation	1	(1.5)		
Gastric bypass	1	(1.5)		
Haemorrhoid operation	1	(1.5)	1	(0.7)
Mammoplasty	1	(1.5)		
Metabolic surgery	1	(1.5)		
Muscle operation	1	(1.5)		
Nasal septal operation	1	(1.5)	1	(0.7)
Open reduction of fracture	1	(1.5)		
Salpingo-oophorectomy	1	(1.5)		
Spinal decompression	1	(1.5)		
Aortic bypass			2	(1.5)
Carpal tunnel decompression			2	(1.5)
Explorative laparotomy			2	(1.5)
Foot operation			2	(1.5)
Hernia repair			2	(1.5)
Inguinal hernia repair			2	(1.5)
Limb operation			2	(1.5)
Renal stone removal			2	(1.5)
Strabismus correction			2	(1.5)
Abdominal hernia repair			1	(0.7)
Adenoidectomy			1	(0.7)
Adenotonsillectomy			1	(0.7)
Ankle arthroplasty			1	(0.7)
Ankle operation			1	(0.7)
Bone lesion excision			1	(0.7)
Bone operation			1	(0.7)
Carotid artery bypass			1	(0.7)
Cataract operation			1	(0.7)
Colectomy			1	(0.7)
Endodontic procedure			1	(0.7)
Fracture treatment			1	(0.7)
Gingival graft			1	(0.7)
Hernia hiatus repair			1	(0.7)
Incisional drainage			1	(0.7)
Intraocular lens implant			1	(0.7)
Keratomileusis			1	(0.7)
Ligament operation			1	(0.7)
Lithotripsy			1	(0.7)
Myopia correction			1	(0.7)
Nasal operation			1	(0.7)
Nasal polypectomy			1	(0.7)
Oesophagogastric fundoplasty			1	(0.7)
Oral surgery			1	(0.7)
Ovarian cystectomy			1	(0.7)
Papilloma excision			1	(0.7)
Rectal prolapse repair			1	(0.7)
Rhinoplasty			1	(0.7)
Sinus operation			1	(0.7)
Skin graft			1	(0.7)
Spinal laminectomy			1	(0.7)
Spinal operation			1	(0.7)
Splenectomy			1	(0.7)
Stent placement			1	(0.7)
Tenoplasty			1	(0.7)
Toe operation			1	(0.7)
Umbilical hernia repair			1	(0.7)
Vasectomy			1	(0.7)
Vascular disorders				
Kawasaki's disease	1	(1.5)		
Hypertension			1	(0.7)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.103.3.1: Total, Severe [IGA=4], Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
Analysis set				
N	60		116	
Cardiac disorders				
Arrhythmia			1	(0.9)
Myocardial infarction			1	(0.9)
Pericarditis			1	(0.9)
Wolff-Parkinson-White syndrome			1	(0.9)
Congenital, familial and genetic disorders				
Ventricular septal defect	1	(1.7)		
Eye disorders				
Conjunctivitis allergic	2	(3.3)	1	(0.9)
Cataract	1	(1.7)	2	(1.7)
Atopic keratoconjunctivitis	1	(1.7)		
Blepharitis	1	(1.7)		
Keratoconus	1	(1.7)		
Myopia	1	(1.7)	1	(0.9)
Retinal detachment	1	(1.7)	1	(0.9)
Gastrointestinal disorders				
Haemorrhoids	1	(1.7)	1	(0.9)
Abdominal adhesions			1	(0.9)
Gastrooesophageal reflux disease			1	(0.9)
Peptic ulcer			1	(0.9)
General disorders and administration site conditions				
Inflammation			1	(0.9)
Hepatobiliary disorders				
Hepatitis			1	(0.9)
Immune system disorders				
Food allergy			2	(1.7)
Allergy to animal			1	(0.9)
Drug hypersensitivity			1	(0.9)
Seasonal allergy			1	(0.9)
Infections and infestations				
Eczema herpeticum	2	(3.3)	3	(2.6)
Herpes simplex	2	(3.3)	1	(0.9)
Staphylococcal skin infection	2	(3.3)		
Impetigo	1	(1.7)	3	(2.6)
Conjunctivitis			2	(1.7)
Herpes zoster	1	(1.7)	2	(1.7)
Cellulitis	1	(1.7)	1	(0.9)
Chronic sinusitis	1	(1.7)		
Fungal infection	1	(1.7)		
Gastrointestinal candidiasis	1	(1.7)		
Herpes virus infection	1	(1.7)		
Oral herpes	1	(1.7)	1	(0.9)
Osteomyelitis	1	(1.7)		
Staphylococcal infection	1	(1.7)		
Acne pustular			1	(0.9)
Appendicitis			1	(0.9)
Body tinea			1	(0.9)
Bronchitis			1	(0.9)
Chronic tonsillitis			1	(0.9)
Croup infectious			1	(0.9)
Dermatitis infected			1	(0.9)
Furuncle			1	(0.9)
Keratitis viral			1	(0.9)
Otitis media			1	(0.9)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.103.3.1: Total, Severe [IGA=4], Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
Infections and infestations				
Pilonidal cyst			1	(0.9)
Pneumonia			1	(0.9)
Sinusitis			1	(0.9)
Tinea cruris			1	(0.9)
Tonsillitis			1	(0.9)
Urinary tract infection bacterial			1	(0.9)
Injury, poisoning and procedural complications				
Foot fracture	2	(3.3)	1	(0.9)
Upper limb fracture			2	(1.7)
Radius fracture	1	(1.7)		
Clavicle fracture			1	(0.9)
Concussion			1	(0.9)
Jaw fracture			1	(0.9)
Ligament rupture			1	(0.9)
Meniscus injury			1	(0.9)
Investigations				
Arthroscopy	1	(1.7)	1	(0.9)
Endoscopy upper gastrointestinal tract	1	(1.7)		
Blood creatinine increased			1	(0.9)
Hysteroscopy			1	(0.9)
Metabolism and nutrition disorders				
Protein deficiency	1	(1.7)		
Musculoskeletal and connective tissue disorders				
Back pain			1	(0.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acanthoma	1	(1.7)		
Meningioma	1	(1.7)		
Lip squamous cell carcinoma			1	(0.9)
Nervous system disorders				
Cerebrovascular accident	1	(1.7)	1	(0.9)
Hydrocephalus	1	(1.7)		
Pregnancy, puerperium and perinatal conditions				
Abortion			1	(0.9)
Gestational hypertension			1	(0.9)
Psychiatric disorders				
Depression	1	(1.7)	3	(2.6)
Depressed mood			1	(0.9)
Drug use disorder			1	(0.9)
Renal and urinary disorders				
Glomerulonephritis			1	(0.9)
Nephrolithiasis			1	(0.9)
Reproductive system and breast disorders				
Uterine polyp			1	(0.9)
Respiratory, thoracic and mediastinal disorders				
Asthma	1	(1.7)	10	(8.6)
Nasal inflammation	1	(1.7)		
Nasal polyps	1	(1.7)		
Nasal septum deviation	1	(1.7)		
Sleep apnoea syndrome			1	(0.9)
Skin and subcutaneous tissue disorders				
Neurodermatitis	1	(1.7)		

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Table 1.7.103.3.1: Total, Severe [IGA=4], Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Severe [IGA=4]		
Skin and subcutaneous tissue disorders		
Acne		1 (0.9)
Dyshidrotic eczema		1 (0.9)
Eczema		1 (0.9)
Hypersensitivity vasculitis		1 (0.9)
Psoriasis		1 (0.9)
Social circumstances		
Postmenopause		1 (0.9)
Surgical and medical procedures		
Tonsillectomy	1 (1.7)	6 (5.2)
Appendicectomy	2 (3.3)	5 (4.3)
Corneal transplant	2 (3.3)	
Eye operation	2 (3.3)	
Haemorrhoid operation	2 (3.3)	
Cardiac ablation		3 (2.6)
Cataract operation	1 (1.7)	3 (2.6)
Hysterectomy		3 (2.6)
Caesarean section	1 (1.7)	2 (1.7)
Vasectomy	1 (1.7)	2 (1.7)
Arthrodesis	1 (1.7)	
Craniotomy	1 (1.7)	
Cyst removal	1 (1.7)	
Endodontic procedure	1 (1.7)	
Heart valve replacement	1 (1.7)	
Keratoplasty	1 (1.7)	
Knee operation	1 (1.7)	
Laser therapy	1 (1.7)	
Ligament operation	1 (1.7)	1 (0.9)
Nasal operation	1 (1.7)	1 (0.9)
Nasal septal operation	1 (1.7)	
Plastic surgery	1 (1.7)	
Spinal fusion surgery	1 (1.7)	1 (0.9)
Steroid therapy	1 (1.7)	
Transfusion	1 (1.7)	
Turbinoplasty	1 (1.7)	
Uterine dilation and curettage	1 (1.7)	1 (0.9)
Adenoidectomy		1 (0.9)
Angioplasty		1 (0.9)
Balneotherapy		1 (0.9)
Brain lobectomy		1 (0.9)
Cardiac resynchronisation therapy		1 (0.9)
Circumcision		1 (0.9)
Endometrial ablation		1 (0.9)
Eye laser surgery		1 (0.9)
Eyelid operation		1 (0.9)
Female sterilisation		1 (0.9)
Foot operation		1 (0.9)
Gastric bypass		1 (0.9)
Hepatitis B immunisation		1 (0.9)
Hepatitis immunisation		1 (0.9)
Immunisation		1 (0.9)
Implantable defibrillator insertion		1 (0.9)
In vitro fertilisation		1 (0.9)
Inguinal hernia repair		1 (0.9)
Intervertebral disc operation		1 (0.9)
Intraocular lens implant		1 (0.9)
Meniscus operation		1 (0.9)
Myomectomy		1 (0.9)
Nasal polypectomy		1 (0.9)
Oophorectomy		1 (0.9)
Osteosynthesis		1 (0.9)
Otoplasty		1 (0.9)

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Table 1.7.103.3.1: Total, Severe [IGA=4], Past medical history by SOC and Preferred term, LP0162-1339

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Severe [IGA=4]		
Surgical and medical procedures		
Peritoneal adhesions division		1 (0.9)
Phototherapy		1 (0.9)
Renal stone removal		1 (0.9)
Spinal operation		1 (0.9)
Strabismus correction		1 (0.9)
Toe operation		1 (0.9)
Uvulectomy		1 (0.9)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.103.4.1: Total, Moderate [IGA=3], Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Moderate [IGA=3]				
Analysis set				
N	70		68	
Blood and lymphatic system disorders				
Iron deficiency anaemia	1	(1.4)		
Cardiac disorders				
Bundle branch block left	1	(1.4)		
Cardiac failure	1	(1.4)		
Congenital, familial and genetic disorders				
Phimosis			1	(1.5)
Endocrine disorders				
Thyroid mass			1	(1.5)
Basedow's disease	1	(1.4)		
Eye disorders				
Conjunctivitis allergic	2	(2.9)	1	(1.5)
Corneal oedema	1	(1.4)		
Gastrointestinal disorders				
Haemorrhoids			1	(1.5)
General disorders and administration site conditions				
Hernia			1	(1.5)
Hypothermia			1	(1.5)
Dysplasia	1	(1.4)		
Immune system disorders				
Mite allergy			1	(1.5)
Seasonal allergy			1	(1.5)
Corneal graft rejection	1	(1.4)		
Hypersensitivity	1	(1.4)		
Infections and infestations				
Impetigo	6	(8.6)	4	(5.9)
Herpes zoster	5	(7.1)	2	(2.9)
Herpes simplex	1	(1.4)	4	(5.9)
Eczema herpeticum	4	(5.7)		
Appendicitis	2	(2.9)		
Oral herpes	2	(2.9)		
Varicella	2	(2.9)	1	(1.5)
Bacterial infection			1	(1.5)
Cellulitis			1	(1.5)
Infection parasitic			1	(1.5)
Meningitis viral			1	(1.5)
Otitis media			1	(1.5)
Post procedural infection			1	(1.5)
Dermatitis infected	1	(1.4)		
Enterobiasis	1	(1.4)		
Epiglottitis	1	(1.4)		
Helicobacter gastritis	1	(1.4)		
Infectious mononucleosis	1	(1.4)		
Meningitis	1	(1.4)		
Mumps	1	(1.4)		
Rhinitis	1	(1.4)		
Tinea cruris	1	(1.4)		
Tuberculosis	1	(1.4)		
Upper respiratory tract infection	1	(1.4)		
Urinary tract infection	1	(1.4)		
Injury, poisoning and procedural complications				
Upper limb fracture	1	(1.4)		

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Table 1.7.103.4.1: Total, Moderate [IGA=3], Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Moderate [IGA=3]				
Injury, poisoning and procedural complications				
Upper limb fracture			2	(2.9)
Facial bones fracture	1	(1.4)	1	(1.5)
Ligament sprain			1	(1.5)
Post-traumatic neck syndrome			1	(1.5)
Wrist fracture			1	(1.5)
Chillblains	1	(1.4)		
Humerus fracture	1	(1.4)		
Joint dislocation	1	(1.4)		
Joint injury	1	(1.4)		
Ligament injury	1	(1.4)		
Multiple fractures	1	(1.4)		
Wound secretion	1	(1.4)		
Investigations				
Skin test	1	(1.4)		
Musculoskeletal and connective tissue disorders				
Joint contracture			1	(1.5)
Osteoarthritis	1	(1.4)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Hodgkin's disease			1	(1.5)
Acanthoma	1	(1.4)		
Anogenital warts	1	(1.4)		
Benign pancreatic neoplasm	1	(1.4)		
Breast cancer	1	(1.4)		
Nervous system disorders				
Cerebral ischaemia			1	(1.5)
Migraine	1	(1.4)		
Restless legs syndrome	1	(1.4)		
Pregnancy, puerperium and perinatal conditions				
HELLP syndrome	1	(1.4)		
Psychiatric disorders				
Depression			2	(2.9)
Anxiety			1	(1.5)
Panic attack			1	(1.5)
Alcoholism	1	(1.4)		
Drug use disorder	1	(1.4)		
Renal and urinary disorders				
Renal colic			1	(1.5)
Ureterolithiasis			1	(1.5)
Acute kidney injury	1	(1.4)		
Hydronephrosis	1	(1.4)		
Reproductive system and breast disorders				
Ovarian cyst			1	(1.5)
Varicocele			1	(1.5)
Respiratory, thoracic and mediastinal disorders				
Asthma			3	(4.4)
Rhinitis allergic			1	(1.5)
Maxillary sinus pseudocyst	1	(1.4)		
Skin and subcutaneous tissue disorders				
Alopecia			2	(2.9)
Dermatitis contact	2	(2.9)	1	(1.5)
Acne	1	(1.4)		
Acne conglobata	1	(1.4)		
Dermal cyst	1	(1.4)		
Surgical and medical procedures				
Appendicectomy	4	(5.7)		

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Table 1.7.103.4.1: Total, Moderate [IGA=3], Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Moderate [IGA=3]		
Surgical and medical procedures		
Appendicectomy		1 (1.5)
Tonsillectomy		3 (4.4)
Caesarean section	1 (1.4)	2 (2.9)
Cyst removal		2 (2.9)
Hysterectomy	1 (1.4)	2 (2.9)
Adenoidectomy	2 (2.9)	1 (1.5)
Immunisation	2 (2.9)	
Abscess drainage		1 (1.5)
Amygdalotomy		1 (1.5)
Bunion operation		1 (1.5)
Cataract operation		1 (1.5)
Circumcision		1 (1.5)
Female genital operation		1 (1.5)
Fracture treatment		1 (1.5)
Hepatitis B immunisation		1 (1.5)
Inguinal hernia repair		1 (1.5)
Ligament operation		1 (1.5)
Meniscus operation	1 (1.4)	1 (1.5)
Meniscus removal		1 (1.5)
Nasal septal operation	1 (1.4)	1 (1.5)
Thyroidectomy		1 (1.5)
Turbinoplasty		1 (1.5)
UV light therapy		1 (1.5)
Wisdom teeth removal	1 (1.4)	1 (1.5)
Benign tumour excision	1 (1.4)	
Cardiac ablation	1 (1.4)	
Cholecystectomy	1 (1.4)	
Jaw operation	1 (1.4)	
Keratoplasty	1 (1.4)	
Large intestinal polypectomy	1 (1.4)	
Oral surgery	1 (1.4)	
Polypectomy	1 (1.4)	
Prophylaxis	1 (1.4)	
Shoulder operation	1 (1.4)	
Stent placement	1 (1.4)	

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Table 1.7.103.4.1: Total, Severe [IGA=4], Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
Analysis set				
N	67		70	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	2	(3.0)		
Neutropenia	1	(1.5)		
Cardiac disorders				
Myocardial ischaemia			1	(1.4)
Pericarditis			1	(1.4)
Congenital, familial and genetic disorders				
Phimosis			1	(1.4)
Endocrine disorders				
Goitre	1	(1.5)		
Eye disorders				
Cataract	1	(1.5)	3	(4.3)
Conjunctivitis allergic	2	(3.0)	2	(2.9)
Keratitis	1	(1.5)	1	(1.4)
Lacrimation increased	1	(1.5)		
Atopic keratoconjunctivitis			1	(1.4)
Keratoconus			1	(1.4)
Retinal detachment			1	(1.4)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	1	(1.5)		
Pancreatitis acute	1	(1.5)		
Hiatus hernia			1	(1.4)
Inguinal hernia			1	(1.4)
Intestinal obstruction			1	(1.4)
Proctitis			1	(1.4)
Immune system disorders				
Oral allergy syndrome	1	(1.5)		
Seasonal allergy			1	(1.4)
Infections and infestations				
Impetigo	4	(6.0)	1	(1.4)
Herpes zoster	1	(1.5)	4	(5.7)
Herpes simplex	2	(3.0)	3	(4.3)
Eczema herpeticum	2	(3.0)	2	(2.9)
Ophthalmic herpes simplex	2	(3.0)		
Erysipelas			2	(2.9)
Conjunctivitis	1	(1.5)	1	(1.4)
Furuncle	1	(1.5)		
Infectious mononucleosis	1	(1.5)		
Meningitis	1	(1.5)		
Otitis externa	1	(1.5)		
Pilonidal cyst	1	(1.5)		
Pneumonia	1	(1.5)		
Postoperative wound infection	1	(1.5)		
Pyelonephritis	1	(1.5)		
Skin bacterial infection	1	(1.5)		
Staphylococcal infection	1	(1.5)		
Groin abscess			1	(1.4)
Herpes ophthalmic			1	(1.4)
Meningitis viral			1	(1.4)
Myringitis			1	(1.4)
Staphylococcal skin infection			1	(1.4)
Vaginal infection			1	(1.4)
Varicella			1	(1.4)
Vulvovaginal candidiasis			1	(1.4)

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Table 1.7.103.4.1: Total, Severe [IGA=4], Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
Injury, poisoning and procedural complications				
Clavicle fracture	1	(1.5)		
Femur fracture	1	(1.5)		
Hand fracture	1	(1.5)		
Joint injury	1	(1.5)		
Ligament rupture	1	(1.5)		
Meniscus injury	1	(1.5)		
Upper limb fracture	1	(1.5)		
Ankle fracture			1	(1.4)
Comminuted fracture			1	(1.4)
Foot fracture			1	(1.4)
Limb fracture			1	(1.4)
Spinal fracture			1	(1.4)
Tibia fracture			1	(1.4)
Investigations				
Arthroscopy	1	(1.5)		
Biopsy breast	1	(1.5)		
Biopsy lymph gland	1	(1.5)		
Metabolism and nutrition disorders				
Hypoproteinaemia	1	(1.5)		
Starvation	1	(1.5)		
Lactose intolerance			1	(1.4)
Musculoskeletal and connective tissue disorders				
Bursitis	1	(1.5)		
Intervertebral disc protrusion	1	(1.5)		
Osteochondrosis	1	(1.5)		
Foot deformity			1	(1.4)
Lumbar spinal stenosis			1	(1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Anogenital warts	1	(1.5)		
Basal cell carcinoma	1	(1.5)		
Bowen's disease	1	(1.5)		
Melanocytic naevus	1	(1.5)		
Papilloma	1	(1.5)		
Prostate cancer	1	(1.5)		
Skin papilloma	1	(1.5)		
Squamous cell carcinoma of skin	1	(1.5)		
Bladder transitional cell carcinoma			1	(1.4)
Renal cancer			1	(1.4)
Sweat gland tumour			1	(1.4)
Testis cancer			1	(1.4)
Nervous system disorders				
Epilepsy	2	(3.0)		
Migraine			1	(1.4)
Paraesthesia			1	(1.4)
Seizure			1	(1.4)
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous	1	(1.5)		
Psychiatric disorders				
Depression	2	(3.0)	3	(4.3)
Insomnia	1	(1.5)		
Mood altered	1	(1.5)		
Stress	1	(1.5)		
Adjustment disorder with depressed mood			1	(1.4)
Renal and urinary disorders				
Nephrolithiasis	2	(3.0)		

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Table 1.7.103.4.1: Total, Severe [IGA=4], Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Severe [IGA=4]				
Reproductive system and breast disorders				
Acquired phimosis	1	(1.5)		
Breast cyst	1	(1.5)		
Polycystic ovaries	1	(1.5)		
Sexual dysfunction			1	(1.4)
Respiratory, thoracic and mediastinal disorders				
Asthma	2	(3.0)	5	(7.1)
Rhinitis allergic	2	(3.0)		
Bronchospasm			1	(1.4)
Pneumothorax			1	(1.4)
Pulmonary embolism			1	(1.4)
Skin and subcutaneous tissue disorders				
Dermatitis exfoliative	1	(1.5)		
Rosacea	1	(1.5)		
Acne			1	(1.4)
Alopecia areata			1	(1.4)
Angioedema			1	(1.4)
Hidradenitis			1	(1.4)
Ingrowing nail			1	(1.4)
Purpura			1	(1.4)
Seborrhoeic dermatitis			1	(1.4)
Surgical and medical procedures				
Tonsillectomy	1	(1.5)	6	(8.6)
Ligament operation	3	(4.5)	1	(1.4)
Caesarean section	2	(3.0)	1	(1.4)
Cholecystectomy	2	(3.0)	1	(1.4)
Appendicectomy			2	(2.9)
Arthrodesis			2	(2.9)
Cataract operation			2	(2.9)
Knee operation			2	(2.9)
Nephrectomy			2	(2.9)
Adenoidectomy	1	(1.5)	1	(1.4)
Carpal tunnel decompression	1	(1.5)	1	(1.4)
Cyst removal	1	(1.5)		
Endometrial ablation	1	(1.5)		
Eye laser surgery	1	(1.5)		
Finger amputation	1	(1.5)		
Hernia repair	1	(1.5)		
Hysterectomy	1	(1.5)	1	(1.4)
In vitro fertilisation	1	(1.5)		
Inguinal hernia repair	1	(1.5)		
Myringotomy	1	(1.5)		
Nasal septal operation	1	(1.5)		
Ovarian cystectomy	1	(1.5)		
Pneumococcal immunisation	1	(1.5)		
Sinus operation	1	(1.5)		
Small intestinal resection	1	(1.5)		
Spinal operation	1	(1.5)		
Strabismus correction	1	(1.5)		
Tooth extraction	1	(1.5)	1	(1.4)
Tumour excision	1	(1.5)		
Turbinoplasty	1	(1.5)	1	(1.4)
Varicose vein operation	1	(1.5)		
Ventriculo-peritoneal shunt	1	(1.5)		
Abscess drainage			1	(1.4)
Adrenalectomy			1	(1.4)
Cervical conisation			1	(1.4)
Eye operation			1	(1.4)
Female sterilisation			1	(1.4)
Hospitalisation			1	(1.4)
Lip lesion excision			1	(1.4)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.103.4.1: Total, Severe [IGA=4], Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Severe [IGA=4]		
Surgical and medical procedures		
Myopia correction		1 (1.4)
Nasal polypectomy		1 (1.4)
Oophorectomy		1 (1.4)
Pleurodesis		1 (1.4)
Skin neoplasm excision		1 (1.4)
UV light therapy		1 (1.4)
Vascular disorders		
Hypertension	1 (1.5)	
Thrombophlebitis	1 (1.5)	1 (1.4)
Infarction		1 (1.4)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.7.104.3.1: Total, Moderate [IGA=3], Atopy history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	136 (100.0)	66 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	25 (18.4)	13 (19.7)
1-3	10 (7.4)	4 (6.1)
More than 3	15 (11.0)	9 (13.6)
Never	84 (61.8)	46 (69.7)
Past	18 (13.2)	3 (4.5)
1-3	8 (5.9)	1 (1.5)
More than 3	10 (7.4)	2 (3.0)
Unknown	9 (6.6)	4 (6.1)
ASTHMA		
Current	59 (43.4)	27 (40.9)
Never	65 (47.8)	27 (40.9)
Past	12 (8.8)	12 (18.2)
ATOPIC KERATOCONJUNCTIVITIS		
Current	3 (2.2)	3 (4.5)
1-3	2 (1.5)	1 (1.5)
More than 3	1 (0.7)	2 (3.0)
Never	121 (89.0)	58 (87.9)
Past	2 (1.5)	2 (3.0)
1-3	2 (1.5)	1 (1.5)
More than 3		1 (1.5)
Unknown	10 (7.4)	3 (4.5)
ECZEMA HERPETICUM		
Never	117 (86.0)	59 (89.4)
Past	10 (7.4)	5 (7.6)
1-3	6 (4.4)	4 (6.1)
More than 3	4 (2.9)	1 (1.5)
Unknown	9 (6.6)	2 (3.0)
FOOD ALLERGY		
Current	41 (30.1)	18 (27.3)
Never	91 (66.9)	43 (65.2)
Past	3 (2.2)	2 (3.0)
Unknown	1 (0.7)	3 (4.5)
HAY FEVER		
Current	71 (52.2)	32 (48.5)
Never	50 (36.8)	30 (45.5)
Past	11 (8.1)	1 (1.5)
Unknown	4 (2.9)	3 (4.5)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.7.104.3.1: Total, Severe [IGA=4], Atopy history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	116 (100.0)	60 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	33 (28.4)	13 (21.7)
1-3	11 (9.5)	2 (3.3)
More than 3	22 (19.0)	11 (18.3)
Never	64 (55.2)	36 (60.0)
Past	16 (13.8)	8 (13.3)
1-3	13 (11.2)	5 (8.3)
More than 3	3 (2.6)	3 (5.0)
Unknown	3 (2.6)	3 (5.0)
ASTHMA		
Current	60 (51.7)	31 (51.7)
Never	39 (33.6)	23 (38.3)
Past	16 (13.8)	6 (10.0)
Unknown	1 (0.9)	
ATOPIC KERATOCONJUNCTIVITIS		
Current	5 (4.3)	2 (3.3)
1-3	4 (3.4)	
More than 3	1 (0.9)	2 (3.3)
Never	107 (92.2)	52 (86.7)
Past		2 (3.3)
1-3		2 (3.3)
Unknown	4 (3.4)	4 (6.7)
ECZEMA HERPETICUM		
Current	1 (0.9)	1 (1.7)
1-3	1 (0.9)	
More than 3		1 (1.7)
Never	101 (87.1)	53 (88.3)
Past	13 (11.2)	4 (6.7)
1-3	12 (10.3)	4 (6.7)
More than 3	1 (0.9)	
Unknown	1 (0.9)	2 (3.3)
FOOD ALLERGY		
Current	48 (41.4)	30 (50.0)
Never	54 (46.6)	26 (43.3)
Past	6 (5.2)	1 (1.7)
Unknown	8 (6.9)	3 (5.0)
HAY FEVER		
Current	70 (60.3)	36 (60.0)
Never	38 (32.8)	21 (35.0)
Past	6 (5.2)	2 (3.3)
Unknown	2 (1.7)	1 (1.7)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.7.104.4.1: Total, Moderate [IGA=3], Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	68 (100.0)	70 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	20 (29.4)	15 (21.4)
More than 3	10 (14.7)	6 (8.6)
Never	35 (51.5)	47 (67.1)
Past	11 (16.2)	8 (11.4)
More than 3	7 (10.3)	5 (7.1)
Unknown	2 (2.9)	
ASTHMA		
Current	26 (38.2)	36 (51.4)
Never	36 (52.9)	32 (45.7)
Past	6 (8.8)	2 (2.9)
ATOPIC KERATOCONJUNCTIVITIS		
Current		2 (2.9)
More than 3		1 (1.4)
Never	63 (92.6)	64 (91.4)
Past	2 (2.9)	4 (5.7)
More than 3		2 (2.9)
Unknown	3 (4.4)	
ECZEMA HERPETICUM		
Never	61 (89.7)	60 (85.7)
Past	4 (5.9)	8 (11.4)
More than 3	1 (1.5)	1 (1.4)
Unknown	3 (4.4)	2 (2.9)
FOOD ALLERGY		
Current	28 (41.2)	25 (35.7)
Never	37 (54.4)	42 (60.0)
Past	1 (1.5)	
Unknown	2 (2.9)	3 (4.3)
HAY FEVER		
Current	36 (52.9)	36 (51.4)
Never	28 (41.2)	31 (44.3)
Past	4 (5.9)	1 (1.4)
Unknown		2 (2.9)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.7.104.4.1: Total, Severe [IGA=4], Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	70 (100.0)	67 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	21 (30.0)	26 (38.8)
More than 3	14 (20.0)	23 (34.3)
Never	37 (52.9)	27 (40.3)
Past	11 (15.7)	13 (19.4)
More than 3	5 (7.1)	7 (10.4)
Unknown	1 (1.4)	1 (1.5)
ASTHMA		
Current	36 (51.4)	38 (56.7)
Never	27 (38.6)	26 (38.8)
Past	7 (10.0)	3 (4.5)
ATOPIC KERATOCONJUNCTIVITIS		
Current		7 (10.4)
More than 3		4 (6.0)
Never	68 (97.1)	53 (79.1)
Past	2 (2.9)	5 (7.5)
More than 3		1 (1.5)
Unknown		2 (3.0)
ECZEMA HERPETICUM		
Never	60 (85.7)	58 (86.6)
Past	10 (14.3)	7 (10.4)
More than 3	3 (4.3)	2 (3.0)
Unknown		2 (3.0)
FOOD ALLERGY		
Current	28 (40.0)	30 (44.8)
Never	41 (58.6)	35 (52.2)
Past	1 (1.4)	2 (3.0)
HAY FEVER		
Current	40 (57.1)	41 (61.2)
Never	23 (32.9)	21 (31.3)
Past	6 (8.6)	4 (6.0)
Unknown	1 (1.4)	1 (1.5)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.7.105.3.1: Total, Moderate [IGA=3], Skin disease history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	136 (100.0)	66 (100.0)
ALOPECIA		
Current	4 (2.9)	4 (6.1)
Never	129 (94.9)	62 (93.9)
Past	3 (2.2)	
CELLULITIS		
Never	125 (91.9)	63 (95.5)
Past	9 (6.6)	2 (3.0)
1-3	8 (5.9)	2 (3.0)
More than 3	1 (0.7)	
Unknown	2 (1.5)	1 (1.5)
HERPES SIMPLEX		
Current	5 (3.7)	2 (3.0)
1-3	1 (0.7)	
More than 3	4 (2.9)	2 (3.0)
Never	105 (77.2)	54 (81.8)
Past	23 (16.9)	9 (13.6)
1-3	16 (11.8)	5 (7.6)
More than 3	7 (5.1)	4 (6.1)
Unknown	3 (2.2)	1 (1.5)
IMPETIGO		
Never	110 (80.9)	58 (87.9)
Past	17 (12.5)	6 (9.1)
1-3	11 (8.1)	5 (7.6)
More than 3	6 (4.4)	1 (1.5)
Unknown	9 (6.6)	2 (3.0)
OTHER SKIN INFECTIONS		
Never	117 (86.0)	55 (83.3)
Past	14 (10.3)	5 (7.6)
Unknown	5 (3.7)	6 (9.1)
VITILIGO		
Current	2 (1.5)	1 (1.5)
Never	134 (98.5)	65 (98.5)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.7.105.3.1: Total, Severe [IGA=4], Skin disease history, LP0162-1339

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	116 (100.0)	60 (100.0)
ALOPECIA		
Current	6 (5.2)	4 (6.7)
Never	108 (93.1)	53 (88.3)
Past	1 (0.9)	1 (1.7)
Unknown	1 (0.9)	2 (3.3)
CELLULITIS		
Never	110 (94.8)	55 (91.7)
Past	3 (2.6)	4 (6.7)
1-3	3 (2.6)	3 (5.0)
More than 3		1 (1.7)
Unknown	3 (2.6)	1 (1.7)
HERPES SIMPLEX		
Current	6 (5.2)	6 (10.0)
1-3	4 (3.4)	2 (3.3)
More than 3	2 (1.7)	4 (6.7)
Never	80 (69.0)	45 (75.0)
Past	28 (24.1)	8 (13.3)
1-3	16 (13.8)	7 (11.7)
More than 3	12 (10.3)	1 (1.7)
Unknown	2 (1.7)	1 (1.7)
IMPETIGO		
Never	91 (78.4)	49 (81.7)
Past	21 (18.1)	7 (11.7)
1-3	17 (14.7)	4 (6.7)
More than 3	4 (3.4)	3 (5.0)
Unknown	4 (3.4)	4 (6.7)
OTHER SKIN INFECTIONS		
Never	99 (85.3)	48 (80.0)
Past	13 (11.2)	9 (15.0)
Unknown	4 (3.4)	3 (5.0)
VITILIGO		
Current	1 (0.9)	3 (5.0)
Never	113 (97.4)	57 (95.0)
Past	1 (0.9)	
Unknown	1 (0.9)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.7.105.4.1: Total, Moderate [IGA=3], Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	68 (100.0)	70 (100.0)
ALOPECIA		
Current	1 (1.5)	2 (2.9)
Never	64 (94.1)	67 (95.7)
Past	2 (2.9)	1 (1.4)
Unknown	1 (1.5)	
CELLULITIS		
Never	65 (95.6)	68 (97.1)
Past	1 (1.5)	2 (2.9)
Unknown	2 (2.9)	
HERPES SIMPLEX		
Current	9 (13.2)	6 (8.6)
More than 3	5 (7.4)	3 (4.3)
Never	43 (63.2)	49 (70.0)
Past	13 (19.1)	14 (20.0)
More than 3	7 (10.3)	9 (12.9)
Unknown	3 (4.4)	1 (1.4)
IMPETIGO		
Never	53 (77.9)	53 (75.7)
Past	14 (20.6)	17 (24.3)
More than 3	2 (2.9)	4 (5.7)
Unknown	1 (1.5)	
OTHER SKIN INFECTIONS		
Never	54 (79.4)	63 (90.0)
Past	9 (13.2)	5 (7.1)
Unknown	5 (7.4)	2 (2.9)
VITILIGO		
Current	1 (1.5)	1 (1.4)
Never	65 (95.6)	69 (98.6)
Past	1 (1.5)	
Unknown	1 (1.5)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.7.105.4.1: Total, Severe [IGA=4], Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	70 (100.0)	67 (100.0)
ALOPECIA		
Current	1 (1.4)	3 (4.5)
Never	69 (98.6)	63 (94.0)
Unknown		1 (1.5)
CELLULITIS		
Never	65 (92.9)	62 (92.5)
Past	2 (2.9)	5 (7.5)
Unknown	3 (4.3)	
HERPES SIMPLEX		
Current	5 (7.1)	6 (9.0)
More than 3	2 (2.9)	5 (7.5)
Never	49 (70.0)	40 (59.7)
Past	15 (21.4)	21 (31.3)
More than 3	5 (7.1)	14 (20.9)
Unknown	1 (1.4)	
IMPETIGO		
Never	55 (78.6)	46 (68.7)
Past	13 (18.6)	19 (28.4)
More than 3	6 (8.6)	9 (13.4)
Unknown	2 (2.9)	2 (3.0)
OTHER SKIN INFECTIONS		
Never	63 (90.0)	54 (80.6)
Past	3 (4.3)	10 (14.9)
Unknown	4 (5.7)	3 (4.5)
VITILIGO		
Never	70 (100.0)	67 (100.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.7.107.3.1: Total, Moderate [IGA=3], Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	136 (100.0)	66 (100.0)
Antibiotics		
Yes	46 (33.8)	23 (34.8)
No	87 (64.0)	39 (59.1)
Unknown	3 (2.2)	4 (6.1)
Azathioprine		
Yes	4 (2.9)	6 (9.1)
More than 12 weeks?		
Yes	3 (2.2)	3 (4.5)
No	1 (0.7)	1 (1.5)
Unknown		2 (3.0)
Reason for discontinuation		
Inadequate efficacy	4 (2.9)	4 (6.1)
Other		1 (1.5)
Side effects		1 (1.5)
No	129 (94.9)	59 (89.4)
Reason for not using		
Contraindications	1 (0.7)	
Risk of side effects	12 (8.8)	8 (12.1)
Other	116 (85.3)	51 (77.3)
Unknown	3 (2.2)	1 (1.5)
Calcineurin inhibitors		
Yes	59 (43.4)	35 (53.0)
No	73 (53.7)	29 (43.9)
Unknown	4 (2.9)	2 (3.0)
Cyclosporine		
Yes	32 (23.5)	20 (30.3)
More than 12 weeks?		
Yes	23 (16.9)	15 (22.7)
No	8 (5.9)	2 (3.0)
Unknown	1 (0.7)	3 (4.5)
Reason for discontinuation		
Inadequate efficacy	18 (13.2)	8 (12.1)
Other	6 (4.4)	5 (7.6)
Side effects	8 (5.9)	7 (10.6)
No	95 (69.9)	43 (65.2)
Reason for not using		
Contraindications	8 (5.9)	2 (3.0)
Risk of side effects	28 (20.6)	18 (27.3)
Other	59 (43.4)	23 (34.8)
Unknown	9 (6.6)	3 (4.5)
Methotrexate		
Yes	9 (6.6)	13 (19.7)
More than 12 weeks?		
Yes	5 (3.7)	4 (6.1)
No	2 (1.5)	4 (6.1)
Unknown	2 (1.5)	5 (7.6)
Reason for discontinuation		
Inadequate efficacy	4 (2.9)	5 (7.6)
Other	5 (3.7)	5 (7.6)
Side effects		3 (4.5)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.3.1: Total, Moderate [IGA=3], Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	122 (89.7)	53 (80.3)
Reason for not using		
Contraindications	1 (0.7)	
Risk of side effects	6 (4.4)	7 (10.6)
Other	115 (84.6)	46 (69.7)
Unknown	5 (3.7)	
Monoclonal antibody/Dupilumab		
Yes	8 (5.9)	7 (10.6)
No	126 (92.6)	59 (89.4)
Unknown	2 (1.5)	
Mycophenolate		
Yes	2 (1.5)	4 (6.1)
More than 12 weeks?		
Yes		1 (1.5)
No	2 (1.5)	2 (3.0)
Unknown		1 (1.5)
Reason for discontinuation		
Inadequate efficacy	1 (0.7)	3 (4.5)
Other		1 (1.5)
Side effects	1 (0.7)	
No	131 (96.3)	61 (92.4)
Reason for not using		
Contraindications	1 (0.7)	
Risk of side effects	11 (8.1)	8 (12.1)
Other	119 (87.5)	53 (80.3)
Unknown	3 (2.2)	1 (1.5)
Other immunosuppressant		
Yes	4 (2.9)	
No	129 (94.9)	65 (98.5)
Unknown	3 (2.2)	1 (1.5)
Phototherapy		
Yes	59 (43.4)	27 (40.9)
No	73 (53.7)	39 (59.1)
Unknown	4 (2.9)	
Systemic steroids		
Yes	66 (48.5)	43 (65.2)
No	66 (48.5)	21 (31.8)
Unknown	4 (2.9)	2 (3.0)
Topical corticosteroids		
Yes	134 (98.5)	64 (97.0)
Highest potency		
High	74 (54.4)	27 (40.9)
Low	5 (3.7)	1 (1.5)
Moderate	29 (21.3)	16 (24.2)
Ultra high	23 (16.9)	16 (24.2)
Unknown	3 (2.2)	4 (6.1)
No	2 (1.5)	2 (3.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.3.1: Total, Moderate [IGA=3], Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Wet wraps		
Yes	12 (8.8)	7 (10.6)
No	117 (86.0)	57 (86.4)
Unknown	7 (5.1)	2 (3.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.3.1: Total, Severe [IGA=4], Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	116 (100.0)	60 (100.0)
Antibiotics		
Yes	61 (52.6)	21 (35.0)
No	51 (44.0)	35 (58.3)
Unknown	4 (3.4)	4 (6.7)
Azathioprine		
Yes	9 (7.8)	6 (10.0)
More than 12 weeks?		
Yes	2 (1.7)	5 (8.3)
No	4 (3.4)	1 (1.7)
Unknown	3 (2.6)	
Reason for discontinuation		
Inadequate efficacy	5 (4.3)	5 (8.3)
Other	1 (0.9)	
Side effects	3 (2.6)	1 (1.7)
No	105 (90.5)	53 (88.3)
Reason for not using		
Contraindications	2 (1.7)	2 (3.3)
Risk of side effects	15 (12.9)	8 (13.3)
Other	88 (75.9)	43 (71.7)
Unknown	2 (1.7)	1 (1.7)
Calcineurin inhibitors		
Yes	68 (58.6)	33 (55.0)
No	41 (35.3)	25 (41.7)
Unknown	6 (5.2)	2 (3.3)
Cyclosporine		
Yes	43 (37.1)	22 (36.7)
More than 12 weeks?		
Yes	37 (31.9)	19 (31.7)
No	5 (4.3)	2 (3.3)
Unknown	1 (0.9)	1 (1.7)
Reason for discontinuation		
Inadequate efficacy	24 (20.7)	11 (18.3)
Other	7 (6.0)	7 (11.7)
Side effects	11 (9.5)	4 (6.7)
No	73 (62.9)	36 (60.0)
Reason for not using		
Contraindications	7 (6.0)	1 (1.7)
Risk of side effects	22 (19.0)	12 (20.0)
Other	44 (37.9)	23 (38.3)
Unknown		2 (3.3)
Methotrexate		
Yes	20 (17.2)	17 (28.3)
More than 12 weeks?		
Yes	11 (9.5)	9 (15.0)
No	3 (2.6)	5 (8.3)
Unknown	6 (5.2)	3 (5.0)
Reason for discontinuation		
Inadequate efficacy	7 (6.0)	6 (10.0)
Other	7 (6.0)	9 (15.0)
Side effects	6 (5.2)	2 (3.3)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.3.1: Total, Severe [IGA=4], Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	94 (81.0)	42 (70.0)
Reason for not using		
Contraindications	3 (2.6)	2 (3.3)
Risk of side effects	13 (11.2)	3 (5.0)
Other	78 (67.2)	37 (61.7)
Unknown	2 (1.7)	1 (1.7)
Monoclonal antibody/Dupilumab		
Yes	6 (5.2)	3 (5.0)
No	109 (94.0)	55 (91.7)
Unknown		2 (3.3)
Mycophenolate		
Yes	5 (4.3)	1 (1.7)
More than 12 weeks?		
Yes	2 (1.7)	
Unknown	3 (2.6)	1 (1.7)
Reason for discontinuation		
Inadequate efficacy	2 (1.7)	1 (1.7)
Other	1 (0.9)	
Side effects	1 (0.9)	
No	104 (89.7)	55 (91.7)
Reason for not using		
Contraindications	2 (1.7)	2 (3.3)
Risk of side effects	14 (12.1)	8 (13.3)
Other	88 (75.9)	45 (75.0)
Unknown	7 (6.0)	4 (6.7)
Other immunosuppressant		
Yes	2 (1.7)	
No	112 (96.6)	56 (93.3)
Unknown	2 (1.7)	4 (6.7)
Phototherapy		
Yes	63 (54.3)	25 (41.7)
No	52 (44.8)	34 (56.7)
Unknown	1 (0.9)	1 (1.7)
Systemic steroids		
Yes	81 (69.8)	42 (70.0)
No	34 (29.3)	16 (26.7)
Unknown	1 (0.9)	2 (3.3)
Topical corticosteroids		
Yes	116 (100.0)	57 (95.0)
Highest potency		
High	57 (49.1)	30 (50.0)
Low	1 (0.9)	
Moderate	19 (16.4)	13 (21.7)
Ultra high	32 (27.6)	13 (21.7)
Unknown	7 (6.0)	1 (1.7)
No		3 (5.0)
Wet wraps		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.3.1: Total, Severe [IGA=4], Previous AD treatments, LP0162-1339

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	22 (19.0)	8 (13.3)
No	89 (76.7)	48 (80.0)
Unknown	5 (4.3)	4 (6.7)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.4.1: Total, Moderate [IGA=3], Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	68 (100.0)	70 (100.0)
Antibiotics		
Yes	24 (35.3)	28 (40.0)
No	44 (64.7)	38 (54.3)
Unknown		4 (5.7)
Azathioprine		
Yes	11 (16.2)	6 (8.6)
More than 12 weeks?		
Yes	7 (10.3)	5 (7.1)
No	3 (4.4)	1 (1.4)
Unknown	1 (1.5)	
Reason for discontinuation		
Inadequate efficacy	6 (8.8)	5 (7.1)
Other		1 (1.4)
Side effects	5 (7.4)	
No	53 (77.9)	63 (90.0)
Reason for not using		
Contraindications	2 (2.9)	5 (7.1)
Risk of side effects	24 (35.3)	20 (28.6)
Other	27 (39.7)	38 (54.3)
Unknown	4 (5.9)	1 (1.4)
Cyclosporine		
Yes	50 (73.5)	51 (72.9)
More than 12 weeks?		
Yes	31 (45.6)	32 (45.7)
No	19 (27.9)	18 (25.7)
Unknown		1 (1.4)
Reason for discontinuation		
Treatment duration >	2 (2.9)	3 (4.3)
Inadequate efficacy	18 (26.5)	22 (31.4)
Other	4 (5.9)	3 (4.3)
Side effects	26 (38.2)	23 (32.9)
No	18 (26.5)	19 (27.1)
Reason for not using		
Contraindications	15 (22.1)	12 (17.1)
Risk of side effects	2 (2.9)	3 (4.3)
Other	1 (1.5)	4 (5.7)
Methotrexate		
Yes	10 (14.7)	12 (17.1)
More than 12 weeks?		
Yes	4 (5.9)	8 (11.4)
No	6 (8.8)	4 (5.7)
Reason for discontinuation		
Inadequate efficacy	6 (8.8)	7 (10.0)
Side effects	4 (5.9)	5 (7.1)
No	56 (82.4)	58 (82.9)
Reason for not using		
Contraindications	8 (11.8)	5 (7.1)
Risk of side effects	19 (27.9)	20 (28.6)
Other	29 (42.6)	33 (47.1)
Unknown	2 (2.9)	
Monoclonal antibody/Dupilumab		
Yes	3 (4.4)	7 (10.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.4.1: Total, Moderate [IGA=3], Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	65 (95.6)	63 (90.0)
Mycophenolate		
Yes	1 (1.5)	2 (2.9)
More than 12 weeks?		
Yes	1 (1.5)	1 (1.4)
No		1 (1.4)
Reason for discontinuation		
Inadequate efficacy	1 (1.5)	1 (1.4)
Side effects		1 (1.4)
No	61 (89.7)	67 (95.7)
Reason for not using		
Contraindications	2 (2.9)	4 (5.7)
Risk of side effects	24 (35.3)	20 (28.6)
Other	34 (50.0)	43 (61.4)
Unknown	6 (8.8)	1 (1.4)
Other immunosuppressant		
Yes	8 (11.8)	4 (5.7)
No	59 (86.8)	65 (92.9)
Unknown	1 (1.5)	1 (1.4)
Phototherapy		
Yes	45 (66.2)	43 (61.4)
No	23 (33.8)	27 (38.6)
Systemic steroids		
Yes	45 (66.2)	40 (57.1)
No	19 (27.9)	26 (37.1)
Unknown	4 (5.9)	4 (5.7)
Topical calcineurin inhibitor		
Yes	47 (69.1)	43 (61.4)
No	16 (23.5)	26 (37.1)
Unknown	5 (7.4)	1 (1.4)
Topical corticosteroids		
Yes	68 (100.0)	69 (98.6)
Highest potency		
High	37 (54.4)	23 (32.9)
Low		1 (1.4)
Moderate	5 (7.4)	10 (14.3)
Ultra high	21 (30.9)	32 (45.7)
Unknown	5 (7.4)	3 (4.3)
No		1 (1.4)
Wet wraps		
Yes	15 (22.1)	10 (14.3)
No	47 (69.1)	59 (84.3)
Unknown	6 (8.8)	1 (1.4)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.4.1: Total, Severe [IGA=4], Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	70 (100.0)	67 (100.0)
Antibiotics		
Yes	31 (44.3)	38 (56.7)
No	32 (45.7)	24 (35.8)
Unknown	7 (10.0)	5 (7.5)
Azathioprine		
Yes	7 (10.0)	12 (17.9)
More than 12 weeks?		
Yes	6 (8.6)	7 (10.4)
No	1 (1.4)	2 (3.0)
Unknown		3 (4.5)
Reason for discontinuation		
Inadequate efficacy	6 (8.6)	9 (13.4)
Other	1 (1.4)	1 (1.5)
Side effects		2 (3.0)
No	61 (87.1)	53 (79.1)
Reason for not using		
Contraindications	3 (4.3)	5 (7.5)
Risk of side effects	20 (28.6)	13 (19.4)
Other	38 (54.3)	35 (52.2)
Unknown	2 (2.9)	2 (3.0)
Cyclosporine		
Yes	54 (77.1)	51 (76.1)
More than 12 weeks?		
Yes	39 (55.7)	39 (58.2)
No	15 (21.4)	12 (17.9)
Reason for discontinuation		
Treatment duration >	3 (4.3)	4 (6.0)
Inadequate efficacy	33 (47.1)	21 (31.3)
Other	3 (4.3)	4 (6.0)
Side effects	15 (21.4)	22 (32.8)
No	16 (22.9)	16 (23.9)
Reason for not using		
Contraindications	13 (18.6)	12 (17.9)
Risk of side effects	2 (2.9)	1 (1.5)
Other	1 (1.4)	3 (4.5)
Methotrexate		
Yes	13 (18.6)	14 (20.9)
More than 12 weeks?		
Yes	11 (15.7)	10 (14.9)
No	2 (2.9)	3 (4.5)
Unknown		1 (1.5)
Reason for discontinuation		
Inadequate efficacy	9 (12.9)	11 (16.4)
Other	1 (1.4)	2 (3.0)
Side effects	3 (4.3)	1 (1.5)
No	57 (81.4)	51 (76.1)
Reason for not using		
Contraindications	3 (4.3)	7 (10.4)
Risk of side effects	20 (28.6)	12 (17.9)
Other	34 (48.6)	32 (47.8)
Unknown		2 (3.0)
Monoclonal antibody/Dupilumab		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.4.1: Total, Severe [IGA=4], Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	6 (8.6)	5 (7.5)
No	62 (88.6)	61 (91.0)
Unknown	2 (2.9)	1 (1.5)
Mycophenolate		
Yes	2 (2.9)	3 (4.5)
More than 12 weeks?		
Yes	2 (2.9)	
No		3 (4.5)
Reason for discontinuation		
Inadequate efficacy	2 (2.9)	2 (3.0)
Side effects		1 (1.5)
No	66 (94.3)	62 (92.5)
Reason for not using		
Contraindications	2 (2.9)	4 (6.0)
Risk of side effects	21 (30.0)	14 (20.9)
Other	43 (61.4)	44 (65.7)
Unknown	2 (2.9)	2 (3.0)
Other immunosuppressant		
Yes	8 (11.4)	8 (11.9)
No	61 (87.1)	58 (86.6)
Unknown	1 (1.4)	1 (1.5)
Phototherapy		
Yes	34 (48.6)	41 (61.2)
No	35 (50.0)	26 (38.8)
Unknown	1 (1.4)	
Systemic steroids		
Yes	52 (74.3)	51 (76.1)
No	17 (24.3)	13 (19.4)
Unknown	1 (1.4)	3 (4.5)
Topical calcineurin inhibitor		
Yes	45 (64.3)	52 (77.6)
No	21 (30.0)	14 (20.9)
Unknown	4 (5.7)	1 (1.5)
Topical corticosteroids		
Yes	70 (100.0)	67 (100.0)
Highest potency		
High	39 (55.7)	31 (46.3)
Moderate	5 (7.1)	5 (7.5)
Ultra high	22 (31.4)	31 (46.3)
Unknown	4 (5.7)	
Wet wraps		
Yes	10 (14.3)	9 (13.4)
No	57 (81.4)	55 (82.1)
Unknown	3 (4.3)	3 (4.5)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.107.4.1: Total, Severe [IGA=4], Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.7.205.3.1: Total, Disease severity (IGA), EASI 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	141 (56.0)	20.2 (9.77;30.56)	1.6 (1.21; 2.03)	2.3 (1.46; 3.53)	0.0002	0.1586
Placebo + TCS	126	45 (35.7)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	136	78 (57.4)	13.5 (-1.07;28.09)	1.3 (0.96; 1.78)	1.7 (0.95; 3.12)	0.0724	
Placebo + TCS	66	29 (43.9)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	116	63 (54.3)	27.6 (13.11;42.17)	2.0 (1.29; 3.20)	3.2 (1.63; 6.27)	0.0005	
Placebo + TCS	60	16 (26.7)					

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 1.7.206.3.1: Total, Disease severity (IGA), EASI 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	83 (32.9)	11.4 (2.13;20.71)	1.5 (1.05; 2.25)	1.8 (1.08; 2.92)	0.0216	0.8138
Placebo + TCS	126	27 (21.4)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	136	48 (35.3)	11.1 (-2.15;24.26)	1.5 (0.89; 2.38)	1.7 (0.87; 3.27)	0.1151	
Placebo + TCS	66	16 (24.2)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	116	35 (30.2)	11.8 (-1.18;24.84)	1.6 (0.90; 3.01)	1.9 (0.89; 4.05)	0.0922	
Placebo + TCS	60	11 (18.3)					

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 1.7.209.3.1: Total, Disease severity (IGA), SCORAD 75, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	60 (23.8)	11.1 (3.16;18.98)	1.9 (1.12; 3.12)	2.1 (1.17; 3.84)	0.0117	0.0719
Placebo + TCS	126	16 (12.7)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	136	32 (23.5)	5.4 (-6.43;17.19)	1.3 (0.71; 2.38)	1.4 (0.66; 2.88)	0.3876	
Placebo + TCS	66	12 (18.2)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	116	28 (24.1)	17.5 (7.38;27.56)	3.6 (1.33; 9.84)	4.4 (1.46;13.04)	0.0046	
Placebo + TCS	60	4 (6.7)					

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.

Table 1.7.210.3.1: Total, Disease severity (IGA), Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	249	115 (46.2)	9.7 (-0.74;20.16)	1.3 (0.97; 1.65)	1.5 (0.96; 2.32)	0.0738	0.4019
Placebo + TCS	126	46 (36.5)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	134	58 (43.3)	5.4 (-9.04;19.83)	1.1 (0.79; 1.65)	1.2 (0.68; 2.28)	0.4688	
Placebo + TCS	66	25 (37.9)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	115	57 (49.6)	14.5 (-0.55;29.65)	1.4 (0.96; 2.09)	1.8 (0.96; 3.49)	0.0668	
Placebo + TCS	60	21 (35.0)					

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.

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Table 1.7.211.3.1: Total, Disease severity (IGA), Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	251	153 (61.0)	17.4 (6.78;27.98)	1.4 (1.12; 1.74)	2.0 (1.30; 3.10)	0.0014	0.0671
Placebo + TCS	126	55 (43.7)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	136	77 (56.6)	8.2 (-6.47;22.84)	1.2 (0.88; 1.56)	1.4 (0.77; 2.51)	0.2760	
Placebo + TCS	66	32 (48.5)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	115	76 (66.1)	27.7 (12.72;42.75)	1.7 (1.22; 2.44)	3.1 (1.64; 6.03)	0.0005	
Placebo + TCS	60	23 (38.3)					

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.

Table 1.7.213.3.1: Total, Disease severity (IGA), POEM improvement of >= 4, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	250	199 (79.6)	16.2 (6.28;26.17)	1.3 (1.08; 1.46)	2.2 (1.38; 3.58)	0.0008	0.0103
Placebo + TCS	123	78 (63.4)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	135	102 (75.6)	4.2 (-9.09;17.56)	1.1 (0.88; 1.27)	1.2 (0.63; 2.43)	0.5271	
Placebo + TCS	63	45 (71.4)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	115	97 (84.3)	29.3 (15.04;43.52)	1.5 (1.20; 1.95)	4.4 (2.15; 8.97)	<.0001	
Placebo + TCS	60	33 (55.0)					

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.

Table 1.7.215.3.1: Total, Disease severity (IGA), DLQI 0/1, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	62 (24.6)	12.7 (4.92;20.47)	2.1 (1.23; 3.47)	2.4 (1.31; 4.43)	0.0040	0.6284
Placebo + TCS	126	15 (11.9)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	136	34 (25.0)	11.4 (0.37;22.47)	1.8 (0.94; 3.60)	2.1 (0.95; 4.71)	0.0643	
Placebo + TCS	66	9 (13.6)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	116	28 (24.1)	14.1 (3.24;25.02)	2.4 (1.06; 5.50)	2.9 (1.11; 7.34)	0.0252	
Placebo + TCS	60	6 (10.0)					

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 1.7.273.3.1: Total, Disease severity (IGA), SCORAD 90, Treatment policy estimand, LP0162-1339, 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 Q2W + TCS	252	21 (8.3)	2.0 (-3.46; 7.39)	1.3 (0.60; 2.85)	1.3 (0.57; 3.14)	0.4989	0.1326
Placebo + TCS	126	8 (6.3)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	136	13 (9.6)	-0.9 (-9.83; 7.94)	0.9 (0.38; 2.17)	0.9 (0.34; 2.38)	0.8332	
Placebo + TCS	66	7 (10.6)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	116	8 (6.9)	5.2 (-0.41;10.87)	4.1 (0.53;32.17)	4.3 (0.53;35.54)	0.1377	
Placebo + TCS	60	1 (1.7)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Region and baseline IGA.

Table 1.7.276.3.1: Total, Disease severity (IGA), Atopic dermatitis flares, all observed data, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	75.03	70 (27.8)	119	158.60	132.5	189.8	0.0050
Placebo + TCS	126	37.94	43 (34.1)	75	197.67	157.6	247.9	0.0050
Moderate [IGA=3]								
Tralokinumab Q2W + TCS	136	40.18	38 (27.9)	63	156.78	122.5	200.7	
Placebo + TCS	66	20.11	15 (22.7)	24	119.32	80.0	178.0	
Severe [IGA=4]								
Tralokinumab Q2W + TCS	116	34.85	32 (27.6)	56	160.69	123.7	208.8	
Placebo + TCS	60	17.83	28 (46.7)	51	286.08	217.4	376.4	

The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. 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. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.7.277.3.1: Total, Disease severity (IGA), Atopic dermatitis flares, excluding data after rescue medication, LP0162-1339, Week 16

Treatment	N	Exposure time (pye)	n (%)	e	Rate (/100pye)	95% confidence interv Lower	Upper	Interaction test p-value (interaction) #
Total								
Tralokinumab Q2W + TCS	252	74.09	69 (27.4)	113	152.51	126.8	183.4	0.0194
Placebo + TCS	126	35.55	40 (31.7)	62	174.42	136.0	223.8	0.0194
Moderate [IGA=3]								
Tralokinumab Q2W + TCS	136	39.51	37 (27.2)	59	149.34	115.7	192.7	
Placebo + TCS	66	19.52	15 (22.7)	22	112.70	74.2	171.2	
Severe [IGA=4]								
Tralokinumab Q2W + TCS	116	34.58	32 (27.6)	54	156.14	119.6	203.9	
Placebo + TCS	60	16.02	25 (41.7)	40	249.62	183.2	340.4	

The number of subjects, percentage of subjects and number of events are summarised and presented by treatment. 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. Q2W: Every 2 weeks, TCS: Topical corticosteroids, n: number of subjects in analysis set. n (%): Number and Proportion of subjects having had atopic dermatitis [AD] flares at Week 16 visit. e: Number of flares from baseline to Week 16. Exposure time(pye): Time in years from treatment start to last visit attended including nominal Week 16 visit. Rate: Total number of flares divided by total time at risk in years multiplied by 100.

Table 1.7.279.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	126	126 7.9 (1.49)		252	251 7.7 (1.51)			
Week 16		112 4.7 (2.59)			226 3.5 (2.21)			
Week 16 chg		112 -3.1 (2.51)	-3.03 (0.21)		226 -4.1 (2.42)	-4.13 (0.15)	-1.10 (-1.61, -0.58) [-0.45 (-0.68, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1255
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.279.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	66	66 7.7 (1.52)		136	136 7.3 (1.64)			
Week 16		60 4.4 (2.46)			124 3.5 (2.26)			
Week 16 chg		60 -3.2 (2.52)	-3.09 (0.29)		124 -3.7 (2.47)	-3.83 (0.20)	-0.75 (-1.45, -0.04) [-0.30 (-0.61, 0.01)]	0.038

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1255
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.279.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	60	60 8.1 (1.45)		116	115 8.1 (1.25)			
Week 16		52 5.0 (2.72)			102 3.5 (2.15)			
Week 16 chg		52 -2.9 (2.50)	-2.98 (0.31)		102 -4.5 (2.29)	-4.49 (0.22)	-1.51 (-2.28, -0.75) [-0.64 (-0.98, -0.30)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1255
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.280.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)			
Week 16		112 3.7 (2.86)			226 2.4 (2.25)			
Week 16 chg		112 -3.3 (2.59)	-3.23 (0.22)		226 -4.4 (2.62)	-4.42 (0.15)	-1.19 (-1.72, -0.67) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0104
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.280.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	66	66 6.8 (2.23)		136	136 6.7 (2.19)			
Week 16		60 3.2 (2.70)			124 2.5 (2.30)			
Week 16 chg		60 -3.6 (2.67)	-3.51 (0.30)		124 -4.0 (2.71)	-4.09 (0.21)	-0.59 (-1.30, 0.13) [-0.22 (-0.53, 0.09)]	0.109

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0104
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.280.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	60	60 7.4 (2.14)		116	115 7.2 (2.02)			
Week 16		52 4.3 (2.95)			102 2.3 (2.20)			
Week 16 chg		52 -2.9 (2.47)	-2.92 (0.31)		102 -4.8 (2.46)	-4.82 (0.22)	-1.90 (-2.65, -1.15) [-0.77 (-1.12, -0.43)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0104
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.281.3.1: Total, Disease severity (IGA), change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
SCORAD Score								
Total								
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)			
Week 16		122 40.9 (23.52)			241 29.4 (18.62)			
Week 16 chg		122 -27.7 (22.50)	-26.93 (1.75)		241 -37.4 (19.31)	-37.74 (1.24)	-10.81 (-15.0, -6.58) [-0.53 (-0.75, -0.31)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0007
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.281.3.1: Total, Disease severity (IGA), change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	66	66 62.4 (9.82)		136	136 59.8 (9.82)		
Week 16		66 31.9 (18.45)			130 26.6 (17.70)		
Week 16 chg		66 -30.6 (21.09)	-29.10 (2.21)		130 -33.0 (18.25)	-33.80 (1.57)	-4.70 (-10.1, 0.66) 0.085 [-0.24 (-0.54, 0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0007
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.281.3.1: Total, Disease severity (IGA), change in SCORAD, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	60	60 75.9 (12.83)		116	116 75.3 (11.84)			
Week 16		56 51.6 (24.50)			111 32.7 (19.20)			
Week 16 chg		56 -24.3 (23.80)	-24.13 (2.69)		111 -42.5 (19.36)	-42.55 (1.91)	-18.42 (-24.9, -11.9) [-0.88 (-1.21, -0.54)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0007
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.282.3.1: Total, Disease severity (IGA), change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score										
Total										
Baseline	126	125	17.2 (7.15)		252	250	17.6 (7.07)			
Week 16		120	8.3 (7.27)			239	5.7 (6.00)			
Week 16 chg		119	-8.8 (7.09)	-8.95 (0.55)		237	-11.8 (7.57)	-11.74 (0.39)	-2.78 (-4.10, -1.47) [-0.38 (-0.60, -0.15)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2557
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.282.3.1: Total, Disease severity (IGA), change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	66	65 16.1 (7.29)		136	135 16.2 (7.12)		
Week 16		63 7.5 (6.39)			128 5.4 (5.98)		
Week 16 chg		62 -8.8 (6.90)	-8.68 (0.71)		127 -10.7 (7.34)	-10.78 (0.50)	-2.11 (-3.81, -0.40) 0.016 [-0.29 (-0.60, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2557
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.282.3.1: Total, Disease severity (IGA), change in DLQI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	60	60 18.4 (6.87)		116	115 19.2 (6.68)			
Week 16		57 9.3 (8.09)			111 6.1 (6.03)			
Week 16 chg		57 -8.7 (7.36)	-9.27 (0.83)		110 -13.1 (7.67)	-12.81 (0.60)	-3.54 (-5.56, -1.53) [-0.47 (-0.79, -0.14)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2557
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.283.3.1: Total, Disease severity (IGA), change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	126	124 22.4 (5.63)		252	250 22.3 (5.09)			
Week 16		120 14.6 (8.22)			239 10.4 (7.20)			
Week 16 chg		118 -7.8 (7.40)	-7.74 (0.65)		237 -11.7 (7.37)	-11.74 (0.46)	-4.00 (-5.56, -2.44) [-0.54 (-0.77, -0.32)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0329
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.283.3.1: Total, Disease severity (IGA), change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	66	64 21.2 (6.00)		136	135 20.6 (5.54)			
Week 16		63 12.8 (7.10)			128 10.0 (7.42)			
Week 16 chg		61 -8.5 (6.81)	-8.16 (0.85)		127 -10.4 (7.12)	-10.57 (0.59)	-2.42 (-4.46, -0.37) [-0.34 (-0.65, -0.04)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0329
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.283.3.1: Total, Disease severity (IGA), change in POEM, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	60	60 23.6 (4.94)		116	115 24.2 (3.67)			
Week 16		57 16.5 (8.97)			111 11.0 (6.93)			
Week 16 chg		57 -7.2 (7.99)	-7.34 (0.98)		110 -13.2 (7.41)	-13.06 (0.70)	-5.72 (-8.11, -3.34) [-0.75 (-1.08, -0.42)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0329
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.285.3.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	126	125	59.4 (23.09)		252	250	59.1 (25.01)		
Week 16		117	71.5 (21.13)			234	75.8 (18.76)		
Week 16 chg		116	12.4 (22.66)	12.50 (1.65)		232	17.0 (24.19)	16.95 (1.17)	4.45 (0.46, 8.43) 0.029 [0.19 (-0.04, 0.41)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5351
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.285.3.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]											
Baseline	66	65	66.0 (20.69)			136	135	64.4 (24.29)			
Week 16		61	74.4 (19.11)				125	77.3 (19.05)			
Week 16 chg		60	9.3 (21.83)	9.74	(2.19)		124	13.3 (21.49)	13.09	(1.52)	3.35 (-1.91, 8.60) 0.211 [0.15 (-0.15, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5351
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.285.3.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	60	60 52.3 (23.58)		116	115 52.9 (24.51)			
Week 16		56 68.3 (22.88)			109 74.2 (18.37)			
Week 16 chg		56 15.7 (23.25)	15.60 (2.51)		108 21.3 (26.43)	21.33 (1.81)	5.74 (-0.37, 11.85) [0.23 (-0.10, 0.55)]	0.065

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5351
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.286.3.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss								
Total								
Baseline	126	126 6.9 (2.72)		252	252 6.5 (2.77)			
Week 16		122 3.2 (3.24)			241 2.2 (2.68)			
Week 16 chg		122 -3.7 (3.20)	-3.44 (0.25)		241 -4.2 (3.34)	-4.29 (0.18)	-0.85 (-1.45, -0.25) [-0.26 (-0.48, -0.04)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0652
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.286.3.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	66	66 6.4 (2.82)		136	136 5.8 (2.85)			
Week 16		66 2.6 (2.88)			130 2.0 (2.59)			
Week 16 chg		66 -3.8 (3.21)	-3.49 (0.32)		130 -3.7 (3.42)	-3.87 (0.23)	-0.38 (-1.16, 0.40) [-0.11 (-0.41, 0.18)]	0.337

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0652
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.286.3.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	60	60 7.4 (2.52)		116	116 7.2 (2.49)			
Week 16		56 3.9 (3.51)			111 2.4 (2.79)			
Week 16 chg		56 -3.5 (3.22)	-3.37 (0.38)		111 -4.7 (3.17)	-4.80 (0.27)	-1.42 (-2.35, -0.50) [-0.45 (-0.77, -0.12)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0652
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Region + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.291.3.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	126	126 30.4 (12.78)		252	252 28.8 (11.97)		
Week 2		124 19.8 (12.98)			251 17.0 (11.25)		
Week 2 chg		124 -10.7 (11.46)	-10.25 (0.87)		251 -11.8 (10.37)	-12.03 (0.61)	-1.78 (-3.86, 0.30) 0.094 [-0.17 (-0.38, 0.05)]
Week 4		126 16.8 (13.62)			247 13.2 (10.47)		
Week 4 chg		126 -13.6 (12.25)	-13.09 (0.86)		247 -15.8 (11.28)	-15.88 (0.61)	-2.78 (-4.86, -0.70) 0.009 [-0.24 (-0.45, -0.02)]
Week 6		125 15.2 (13.41)			247 10.7 (9.46)		
Week 6 chg		125 -15.2 (12.09)	-14.70 (0.87)		247 -18.3 (11.21)	-18.31 (0.61)	-3.62 (-5.70, -1.53) <.001 [-0.31 (-0.53, -0.10)]
Week 8		122 13.6 (12.73)			243 9.3 (8.85)		
Week 8 chg		122 -16.7 (11.39)	-15.95 (0.87)		243 -19.8 (11.30)	-19.68 (0.61)	-3.73 (-5.82, -1.64) <.001 [-0.33 (-0.55, -0.11)]
Week 10		118 13.9 (13.56)			237 8.2 (8.42)		
Week 10 chg		118 -16.2 (11.61)	-15.71 (0.87)		237 -20.7 (12.01)	-20.64 (0.62)	-4.92 (-7.03, -2.82) <.001 [-0.41 (-0.64, -0.19)]
Week 12		119 12.9 (12.82)			238 8.0 (9.27)		
Week 12 chg		119 -17.2 (11.92)	-16.57 (0.87)		238 -21.1 (12.42)	-21.12 (0.62)	-4.55 (-6.65, -2.45) <.001 [-0.37 (-0.59, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.291.3.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	118	13.1 (13.79)		235	7.7 (9.25)		
Week 14 chg	118	-16.9 (13.53)	-16.27 (0.87)	235	-21.4 (12.29)	-21.30 (0.62)	-5.03 (-7.14, -2.93) <.001 [-0.40 (-0.62, -0.17)]
Week 16	123	14.1 (14.89)		241	8.1 (9.15)		
Week 16 chg	123	-16.0 (14.04)	-15.45 (0.87)	241	-20.7 (12.33)	-20.92 (0.62)	-5.47 (-7.56, -3.38) <.001 [-0.42 (-0.64, -0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.291.3.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	66	66 22.9 (6.78)		136	136 22.9 (7.81)			
Week 2		66 14.7 (7.93)			136 14.1 (7.84)			
Week 2 chg		66 -8.2 (8.81)	-8.19 (0.90)		136 -8.7 (7.95)	-8.73 (0.63)	-0.54 (-2.71, 1.63) [-0.07 (-0.36, 0.23)]	0.624
Week 4		66 11.5 (9.61)			131 10.8 (8.04)			
Week 4 chg		66 -11.4 (9.95)	-11.37 (0.90)		131 -12.2 (8.29)	-11.96 (0.64)	-0.58 (-2.76, 1.59) [-0.07 (-0.36, 0.23)]	0.597
Week 6		66 9.4 (7.39)			132 8.6 (6.79)			
Week 6 chg		66 -13.5 (7.96)	-13.49 (0.90)		132 -14.4 (8.26)	-14.17 (0.64)	-0.67 (-2.85, 1.50) [-0.08 (-0.38, 0.21)]	0.542
Week 8		64 8.6 (8.03)			130 7.7 (6.82)			
Week 8 chg		64 -14.1 (7.75)	-14.08 (0.91)		130 -15.4 (8.66)	-15.11 (0.64)	-1.03 (-3.22, 1.15) [-0.12 (-0.42, 0.18)]	0.353
Week 10		63 8.1 (8.13)			129 6.7 (6.35)			
Week 10 chg		63 -14.7 (7.71)	-14.62 (0.91)		129 -16.4 (8.62)	-16.06 (0.64)	-1.44 (-3.63, 0.75) [-0.17 (-0.47, 0.13)]	0.196
Week 12		65 7.9 (8.25)			128 6.5 (8.01)			
Week 12 chg		65 -14.7 (8.08)	-14.81 (0.91)		128 -16.4 (9.07)	-16.29 (0.64)	-1.48 (-3.66, 0.71) [-0.17 (-0.47, 0.13)]	0.184
Week 14		63 7.8 (8.95)			125 6.7 (8.37)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.291.3.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	63	-15.0 (9.18)	-14.89 (0.91)	125	-16.1 (8.85)	-15.84 (0.64)	-0.94 (-3.14, 1.25) [-0.11 (-0.41, 0.20)]	0.399
Week 16	66	8.4 (8.82)		130	6.8 (8.31)			
Week 16 chg	66	-14.6 (8.69)	-14.55 (0.90)	130	-15.9 (8.80)	-15.81 (0.64)	-1.26 (-3.44, 0.91) [-0.14 (-0.44, 0.15)]	0.254

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.291.3.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	60	60 38.7 (12.78)		116	116 35.8 (12.23)		
Week 2		58 25.6 (15.10)			115 20.5 (13.53)		
Week 2 chg		58 -13.6 (13.37)	-12.91 (1.51)		115 -15.4 (11.69)	-15.76 (1.08)	-2.85 (-6.51, 0.81) 0.126 [-0.23 (-0.55, 0.08)]
Week 4		60 22.6 (15.03)			116 15.9 (12.16)		
Week 4 chg		60 -16.0 (14.04)	-15.18 (1.50)		116 -19.9 (12.76)	-20.41 (1.08)	-5.23 (-8.88, -1.59) 0.005 [-0.40 (-0.71, -0.08)]
Week 6		59 21.7 (15.54)			115 13.1 (11.37)		
Week 6 chg		59 -17.2 (15.29)	-16.23 (1.50)		115 -22.7 (12.44)	-23.11 (1.08)	-6.88 (-10.5, -3.23) <.001 [-0.51 (-0.83, -0.19)]
Week 8		58 19.3 (14.54)			113 11.1 (10.46)		
Week 8 chg		58 -19.5 (13.92)	-18.28 (1.51)		113 -24.8 (11.90)	-24.95 (1.08)	-6.67 (-10.3, -3.01) <.001 [-0.53 (-0.85, -0.21)]
Week 10		55 20.6 (15.43)			108 9.9 (10.13)		
Week 10 chg		55 -18.1 (14.74)	-17.05 (1.52)		108 -25.8 (13.42)	-25.95 (1.09)	-8.90 (-12.6, -5.21) <.001 [-0.64 (-0.97, -0.31)]
Week 12		54 19.0 (14.66)			110 9.6 (10.33)		
Week 12 chg		54 -20.1 (14.88)	-18.58 (1.52)		110 -26.6 (13.55)	-26.74 (1.09)	-8.16 (-11.9, -4.47) <.001 [-0.58 (-0.91, -0.25)]
Week 14		55 19.2 (15.79)			110 8.7 (10.10)		

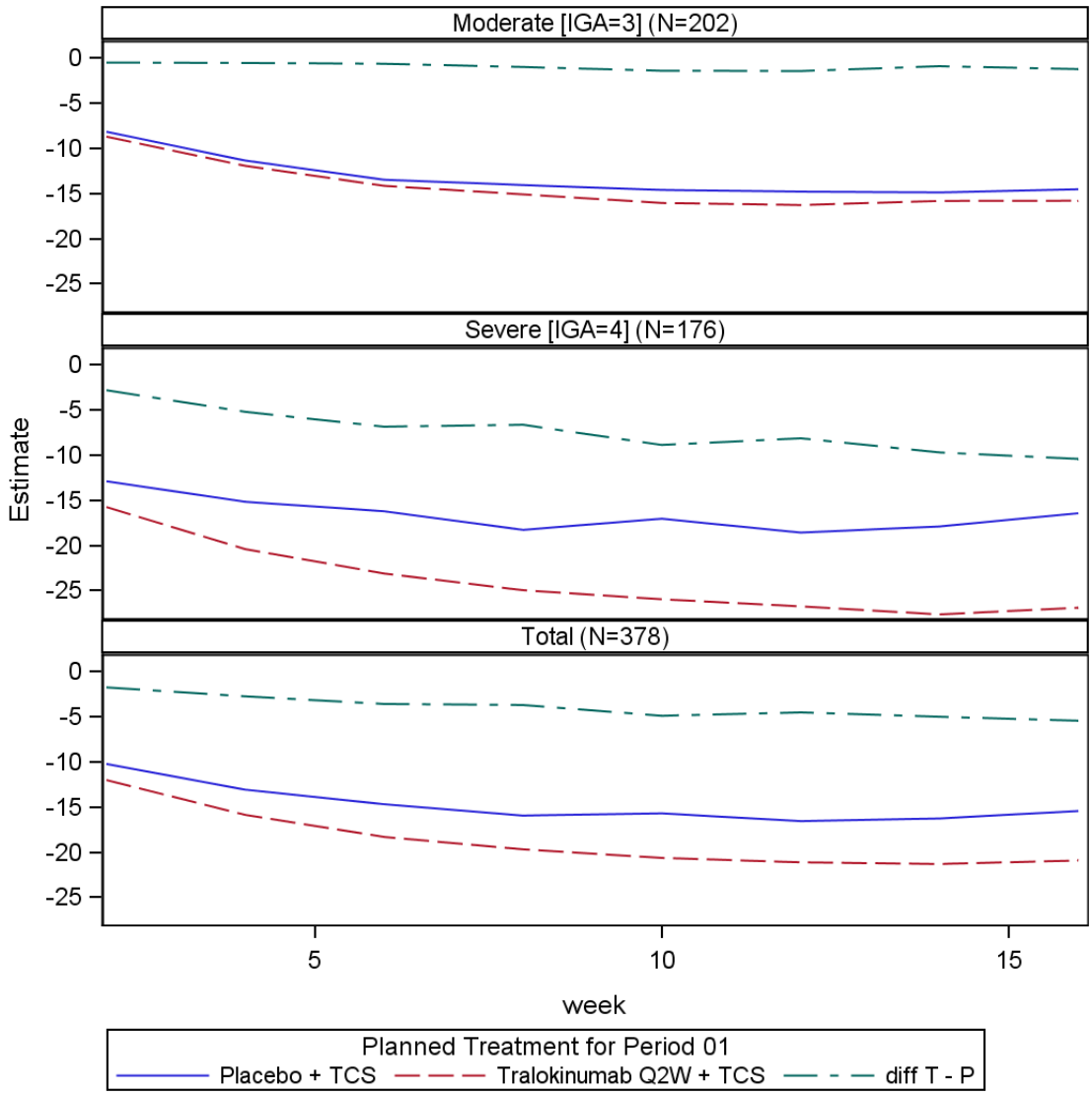
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.7.291.3.1: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	55	-19.1 (17.06)	-17.90 (1.52)	110	-27.4 (12.88)	-27.63 (1.09)	-9.72 (-13.4, -6.04) [-0.68 (-1.01, -0.34)]	<.001
Week 16	57	20.7 (17.60)		111	9.5 (9.87)			
Week 16 chg	57	-17.7 (18.34)	-16.44 (1.51)	111	-26.2 (13.52)	-26.89 (1.08)	-10.44 (-14.1, -6.77) [-0.68 (-1.01, -0.35)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.291.3.2: Total, Disease severity (IGA), change in EASI, Treatment policy estimand, LP0162-1339, 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 1.7.293.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)							
Total							
Baseline	126	126 7.9 (1.49)		252	251 7.7 (1.51)		
Week 1		125 6.5 (1.78)			248 6.2 (1.90)		
Week 1 chg		125 -1.3 (1.50)	-1.27 (0.19)		248 -1.5 (1.56)	-1.50 (0.14)	-0.23 (-0.69, 0.24) 0.336 [-0.15 (-0.36, 0.07)]
Week 2		126 6.0 (2.11)			245 5.5 (2.23)		
Week 2 chg		126 -1.8 (2.00)	-1.80 (0.19)		245 -2.2 (2.02)	-2.19 (0.14)	-0.39 (-0.85, 0.07) 0.097 [-0.19 (-0.41, 0.02)]
Week 3		125 5.8 (2.18)			243 5.0 (2.26)		
Week 3 chg		125 -2.0 (2.05)	-1.97 (0.19)		243 -2.6 (2.15)	-2.65 (0.14)	-0.68 (-1.15, -0.22) 0.004 [-0.32 (-0.54, -0.11)]
Week 4		120 5.5 (2.39)			244 4.8 (2.29)		
Week 4 chg		120 -2.4 (2.21)	-2.31 (0.19)		244 -2.9 (2.21)	-2.92 (0.14)	-0.62 (-1.08, -0.15) 0.009 [-0.28 (-0.50, -0.06)]
Week 5		118 5.2 (2.42)			238 4.5 (2.21)		
Week 5 chg		118 -2.7 (2.31)	-2.62 (0.19)		238 -3.2 (2.19)	-3.19 (0.14)	-0.56 (-1.03, -0.10) 0.018 [-0.25 (-0.47, -0.03)]
Week 6		122 5.1 (2.50)			239 4.3 (2.23)		
Week 6 chg		122 -2.7 (2.39)	-2.68 (0.19)		239 -3.3 (2.26)	-3.30 (0.14)	-0.62 (-1.08, -0.15) 0.009 [-0.27 (-0.49, -0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1623
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 1.7.293.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	116	4.9 (2.48)		231	4.2 (2.27)			
Week 7 chg	116	-2.9 (2.41)	-2.79 (0.19)	231	-3.5 (2.29)	-3.47 (0.14)	-0.68 (-1.15, -0.22) [-0.29 (-0.52, -0.07)]	0.004
Week 8	116	4.9 (2.49)		227	4.0 (2.31)			
Week 8 chg	116	-2.9 (2.38)	-2.81 (0.19)	227	-3.6 (2.35)	-3.60 (0.14)	-0.79 (-1.26, -0.32) [-0.34 (-0.56, -0.11)]	<.001
Week 9	116	4.9 (2.53)		235	3.9 (2.24)			
Week 9 chg	116	-3.0 (2.35)	-2.88 (0.19)	235	-3.7 (2.31)	-3.75 (0.14)	-0.87 (-1.33, -0.40) [-0.37 (-0.60, -0.15)]	<.001
Week 10	114	4.8 (2.56)		235	3.8 (2.27)			
Week 10 chg	114	-3.0 (2.45)	-2.97 (0.19)	235	-3.8 (2.43)	-3.82 (0.14)	-0.85 (-1.31, -0.38) [-0.35 (-0.57, -0.12)]	<.001
Week 11	115	4.8 (2.54)		231	3.6 (2.19)			
Week 11 chg	115	-3.0 (2.48)	-2.96 (0.19)	231	-4.0 (2.39)	-4.03 (0.14)	-1.06 (-1.53, -0.60) [-0.44 (-0.67, -0.21)]	<.001
Week 12	115	4.7 (2.55)		234	3.7 (2.15)			
Week 12 chg	115	-3.1 (2.41)	-2.99 (0.19)	234	-3.9 (2.40)	-3.97 (0.14)	-0.98 (-1.45, -0.51) [-0.41 (-0.63, -0.18)]	<.001
Week 13	115	4.8 (2.53)		233	3.6 (2.19)			
Week 13 chg	115	-3.1 (2.37)	-3.00 (0.19)	233	-4.1 (2.44)	-4.12 (0.14)	-1.12 (-1.59, -0.65) [-0.46 (-0.69, -0.24)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1623
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 1.7.293.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	116	4.7 (2.57)		223	3.6 (2.20)			
Week 14 chg	116	-3.1 (2.42)	-3.00 (0.19)	223	-4.0 (2.49)	-4.05 (0.14)	-1.05 (-1.52, -0.58) [-0.43 (-0.65, -0.20)]	<.001
Week 15	114	4.8 (2.59)		225	3.5 (2.20)			
Week 15 chg	114	-3.0 (2.44)	-3.00 (0.19)	225	-4.1 (2.43)	-4.10 (0.14)	-1.10 (-1.57, -0.63) [-0.45 (-0.68, -0.22)]	<.001
Week 16	112	4.7 (2.59)		226	3.5 (2.21)			
Week 16 chg	112	-3.1 (2.51)	-2.99 (0.19)	226	-4.1 (2.42)	-4.12 (0.14)	-1.13 (-1.60, -0.66) [-0.46 (-0.69, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1623
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 1.7.293.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	66	66 7.7 (1.52)		136	136 7.3 (1.64)		
Week 1		66 6.3 (1.83)			135 6.2 (1.90)		
Week 1 chg		66 -1.4 (1.66)	-1.36 (0.26)		135 -1.2 (1.37)	-1.18 (0.18)	0.17 (-0.45, 0.80) 0.585 [0.12 (-0.18, 0.41)]
Week 2		66 5.8 (2.09)			131 5.4 (2.27)		
Week 2 chg		66 -1.8 (2.04)	-1.76 (0.26)		131 -1.9 (1.91)	-1.88 (0.18)	-0.12 (-0.74, 0.50) 0.706 [-0.06 (-0.36, 0.23)]
Week 3		66 5.6 (2.10)			130 5.1 (2.25)		
Week 3 chg		66 -2.0 (2.13)	-1.94 (0.26)		130 -2.3 (2.07)	-2.32 (0.18)	-0.38 (-1.00, 0.25) 0.234 [-0.18 (-0.48, 0.12)]
Week 4		63 5.2 (2.33)			132 4.8 (2.22)		
Week 4 chg		63 -2.5 (2.25)	-2.36 (0.26)		132 -2.5 (2.10)	-2.53 (0.18)	-0.17 (-0.79, 0.46) 0.601 [-0.08 (-0.38, 0.22)]
Week 5		62 4.8 (2.29)			129 4.4 (2.18)		
Week 5 chg		62 -2.8 (2.34)	-2.74 (0.26)		129 -2.9 (2.19)	-2.92 (0.18)	-0.18 (-0.81, 0.45) 0.569 [-0.08 (-0.38, 0.22)]
Week 6		65 4.8 (2.40)			127 4.2 (2.11)		
Week 6 chg		65 -2.9 (2.46)	-2.76 (0.26)		127 -3.0 (2.18)	-3.02 (0.18)	-0.26 (-0.89, 0.36) 0.411 [-0.12 (-0.41, 0.18)]
Week 7		62 4.6 (2.43)			125 4.2 (2.21)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1623
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 1.7.293.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	62	-3.1 (2.47)	-2.87 (0.26)	125	-3.1 (2.27)	-3.14 (0.18)	-0.27 (-0.90, 0.36) 0.406 [-0.11 (-0.42, 0.19)]
Week 8	62	4.6 (2.43)		123	4.1 (2.28)		
Week 8 chg	62	-3.1 (2.50)	-2.87 (0.26)	123	-3.2 (2.37)	-3.22 (0.18)	-0.35 (-0.98, 0.28) 0.274 [-0.15 (-0.45, 0.16)]
Week 9	63	4.5 (2.43)		125	3.9 (2.18)		
Week 9 chg	63	-3.2 (2.48)	-2.98 (0.26)	125	-3.4 (2.29)	-3.49 (0.18)	-0.51 (-1.13, 0.12) 0.114 [-0.21 (-0.52, 0.09)]
Week 10	60	4.4 (2.45)		126	3.8 (2.27)		
Week 10 chg	60	-3.3 (2.61)	-3.13 (0.26)	126	-3.4 (2.41)	-3.54 (0.18)	-0.41 (-1.04, 0.22) 0.204 [-0.17 (-0.47, 0.14)]
Week 11	61	4.4 (2.41)		126	3.6 (2.10)		
Week 11 chg	61	-3.3 (2.60)	-3.08 (0.26)	126	-3.6 (2.38)	-3.76 (0.18)	-0.68 (-1.31, -0.05) 0.035 [-0.28 (-0.58, 0.03)]
Week 12	61	4.4 (2.38)		124	3.6 (2.14)		
Week 12 chg	61	-3.3 (2.44)	-3.04 (0.26)	124	-3.6 (2.48)	-3.80 (0.18)	-0.76 (-1.39, -0.13) 0.018 [-0.31 (-0.62, -0.00)]
Week 13	60	4.5 (2.38)		123	3.6 (2.15)		
Week 13 chg	60	-3.2 (2.45)	-3.00 (0.26)	123	-3.7 (2.45)	-3.83 (0.18)	-0.84 (-1.47, -0.20) 0.010 [-0.34 (-0.65, -0.03)]
Week 14	62	4.3 (2.50)		122	3.7 (2.24)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1623
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 1.7.293.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	62	-3.4 (2.47)	-3.10 (0.26)	122	-3.5 (2.56)	-3.68 (0.18)	-0.58 (-1.21, 0.05) [-0.23 (-0.54, 0.08)]	0.071
Week 15	59	4.4 (2.43)		123	3.6 (2.23)			
Week 15 chg	59	-3.3 (2.51)	-3.07 (0.26)	123	-3.7 (2.48)	-3.78 (0.18)	-0.72 (-1.35, -0.08) [-0.29 (-0.60, 0.02)]	0.026
Week 16	60	4.4 (2.46)		124	3.5 (2.26)			
Week 16 chg	60	-3.2 (2.52)	-3.03 (0.26)	124	-3.7 (2.47)	-3.90 (0.18)	-0.87 (-1.51, -0.24) [-0.35 (-0.66, -0.04)]	0.007

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1623
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 1.7.293.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]											
Baseline	60	60	8.1 (1.45)			116	115	8.1 (1.25)			
Week 1		59	6.8 (1.68)				113	6.2 (1.91)			
Week 1 chg		59	-1.2 (1.32)	-1.19	(0.28)		113	-1.9 (1.68)	-1.87	(0.20)	-0.68 (-1.36, 0.00) 0.051 [-0.43 (-0.75, -0.12)]
Week 2		60	6.2 (2.13)				114	5.5 (2.20)			
Week 2 chg		60	-1.9 (1.97)	-1.85	(0.28)		114	-2.5 (2.10)	-2.54	(0.20)	-0.69 (-1.37, -0.01) 0.048 [-0.33 (-0.65, -0.02)]
Week 3		59	6.1 (2.26)				113	5.0 (2.28)			
Week 3 chg		59	-2.0 (1.98)	-2.01	(0.28)		113	-3.1 (2.16)	-3.06	(0.20)	-1.05 (-1.73, -0.36) 0.003 [-0.50 (-0.82, -0.18)]
Week 4		57	5.9 (2.42)				112	4.7 (2.38)			
Week 4 chg		57	-2.2 (2.16)	-2.25	(0.28)		112	-3.4 (2.26)	-3.39	(0.20)	-1.14 (-1.83, -0.46) 0.001 [-0.51 (-0.84, -0.19)]
Week 5		56	5.6 (2.52)				109	4.5 (2.25)			
Week 5 chg		56	-2.5 (2.27)	-2.48	(0.28)		109	-3.5 (2.16)	-3.50	(0.20)	-1.02 (-1.71, -0.34) 0.004 [-0.47 (-0.79, -0.14)]
Week 6		57	5.5 (2.56)				112	4.4 (2.36)			
Week 6 chg		57	-2.5 (2.31)	-2.57	(0.28)		112	-3.7 (2.30)	-3.62	(0.20)	-1.05 (-1.74, -0.37) 0.003 [-0.46 (-0.78, -0.14)]
Week 7		54	5.3 (2.51)				106	4.2 (2.33)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1623
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 1.7.293.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	54	-2.7 (2.33)	-2.70 (0.28)	106	-3.9 (2.24)	-3.88 (0.20)	-1.18 (-1.87, -0.50) <.001 [-0.52 (-0.85, -0.19)]
Week 8	54	5.4 (2.52)		104	3.9 (2.35)		
Week 8 chg	54	-2.7 (2.23)	-2.73 (0.28)	104	-4.1 (2.24)	-4.06 (0.20)	-1.33 (-2.02, -0.64) <.001 [-0.60 (-0.93, -0.26)]
Week 9	53	5.3 (2.60)		110	3.9 (2.31)		
Week 9 chg	53	-2.7 (2.17)	-2.74 (0.28)	110	-4.1 (2.27)	-4.08 (0.20)	-1.34 (-2.03, -0.65) <.001 [-0.60 (-0.93, -0.26)]
Week 10	54	5.3 (2.61)		109	3.8 (2.28)		
Week 10 chg	54	-2.7 (2.26)	-2.78 (0.28)	109	-4.2 (2.40)	-4.16 (0.20)	-1.37 (-2.06, -0.69) <.001 [-0.58 (-0.92, -0.25)]
Week 11	54	5.2 (2.63)		105	3.6 (2.31)		
Week 11 chg	54	-2.7 (2.33)	-2.80 (0.28)	105	-4.5 (2.33)	-4.37 (0.20)	-1.57 (-2.25, -0.88) <.001 [-0.67 (-1.01, -0.34)]
Week 12	54	5.1 (2.70)		110	3.8 (2.17)		
Week 12 chg	54	-2.9 (2.37)	-2.91 (0.28)	110	-4.3 (2.29)	-4.20 (0.20)	-1.29 (-1.98, -0.60) <.001 [-0.56 (-0.89, -0.23)]
Week 13	55	5.1 (2.67)		110	3.5 (2.24)		
Week 13 chg	55	-2.9 (2.29)	-2.99 (0.28)	110	-4.5 (2.36)	-4.48 (0.20)	-1.48 (-2.17, -0.80) <.001 [-0.63 (-0.97, -0.30)]
Week 14	54	5.2 (2.61)		101	3.4 (2.15)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1623
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.

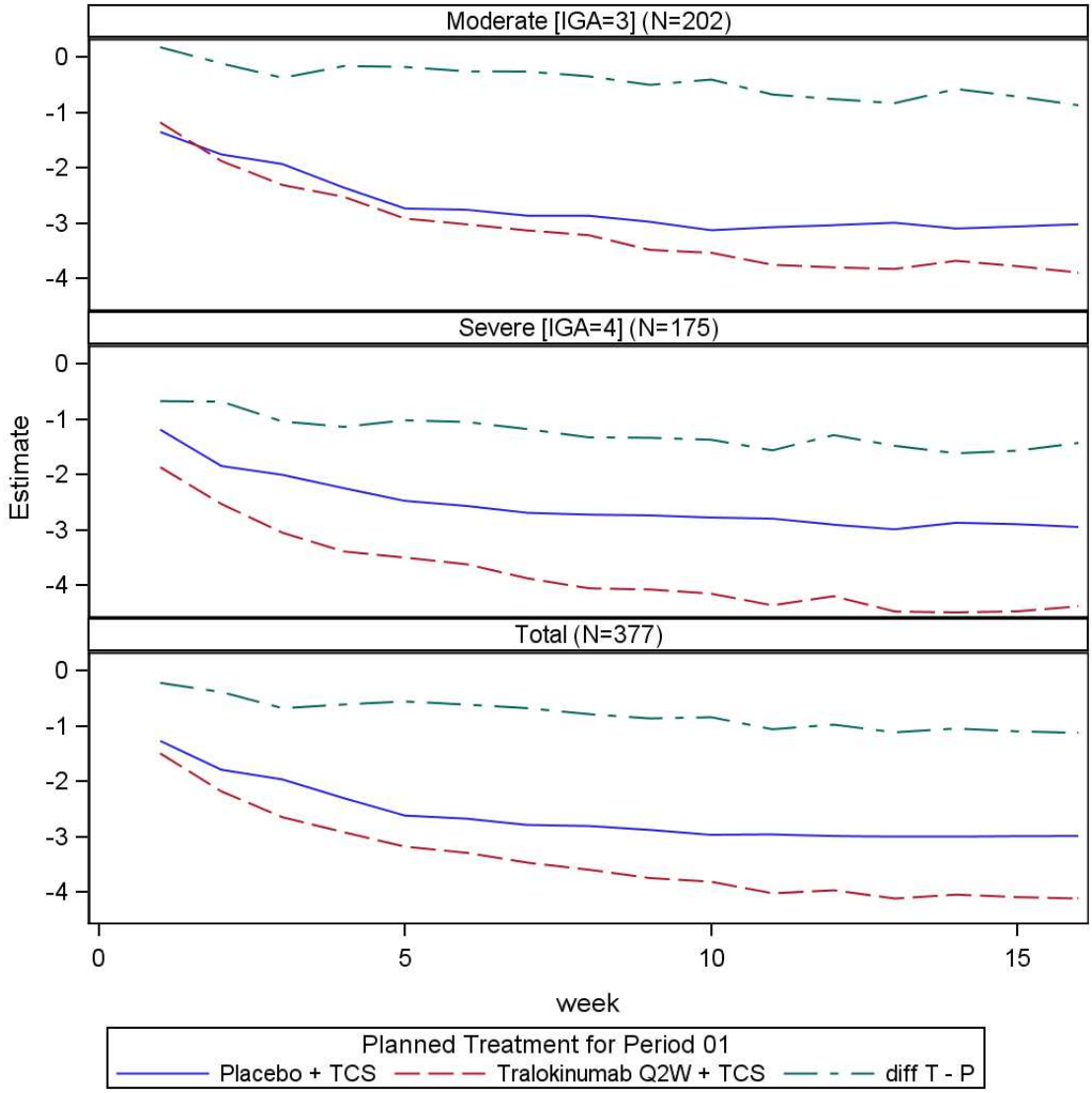
Table 1.7.293.3.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	54	-2.8 (2.35)	-2.88 (0.28)	101	-4.6 (2.27)	-4.50 (0.21)	-1.62 (-2.31, -0.93) [-0.70 (-1.04, -0.37)]	<.001
Week 15	55	5.2 (2.71)		102	3.4 (2.17)			
Week 15 chg	55	-2.8 (2.35)	-2.90 (0.28)	102	-4.6 (2.28)	-4.47 (0.21)	-1.57 (-2.26, -0.89) [-0.68 (-1.02, -0.34)]	<.001
Week 16	52	5.0 (2.72)		102	3.5 (2.15)			
Week 16 chg	52	-2.9 (2.50)	-2.95 (0.28)	102	-4.5 (2.29)	-4.39 (0.21)	-1.43 (-2.12, -0.74) [-0.61 (-0.95, -0.27)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1623
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.

12MAY21 16:42 LP0162-Payer /p_mmrm3/t_t_igag_e93_39_w16.txt

Figure 1.7.293.3.2: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy estimand, LP0162-1339, 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 1.7.295.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	126	126 7.1 (2.20)		252	251 6.9 (2.12)		
Week 1		125 5.7 (2.39)			248 5.3 (2.33)		
Week 1 chg		125 -1.4 (1.62)	-1.38 (0.20)		248 -1.6 (1.68)	-1.56 (0.14)	-0.18 (-0.65, 0.30) 0.468 [-0.11 (-0.32, 0.11)]
Week 2		126 5.1 (2.66)			245 4.5 (2.54)		
Week 2 chg		126 -1.9 (2.16)	-1.90 (0.20)		245 -2.4 (2.19)	-2.35 (0.14)	-0.45 (-0.93, 0.03) 0.066 [-0.21 (-0.42, 0.01)]
Week 3		125 4.9 (2.61)			243 4.0 (2.57)		
Week 3 chg		125 -2.2 (2.17)	-2.11 (0.20)		243 -2.9 (2.33)	-2.90 (0.14)	-0.79 (-1.27, -0.31) 0.001 [-0.35 (-0.56, -0.13)]
Week 4		120 4.6 (2.69)			244 3.8 (2.59)		
Week 4 chg		120 -2.5 (2.26)	-2.44 (0.20)		244 -3.1 (2.41)	-3.15 (0.14)	-0.70 (-1.18, -0.22) 0.004 [-0.30 (-0.52, -0.08)]
Week 5		118 4.3 (2.71)			238 3.4 (2.50)		
Week 5 chg		118 -2.8 (2.32)	-2.70 (0.20)		238 -3.5 (2.40)	-3.48 (0.14)	-0.78 (-1.26, -0.30) 0.002 [-0.33 (-0.55, -0.11)]
Week 6		122 4.3 (2.76)			239 3.2 (2.50)		
Week 6 chg		122 -2.7 (2.43)	-2.70 (0.20)		239 -3.6 (2.53)	-3.61 (0.14)	-0.91 (-1.39, -0.43) <.001 [-0.36 (-0.58, -0.14)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0248
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 1.7.295.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	116	4.0 (2.76)		231	3.0 (2.47)			
Week 7 chg	116	-3.0 (2.49)	-2.97 (0.20)	231	-3.8 (2.52)	-3.81 (0.14)	-0.84 (-1.32, -0.36) [-0.34 (-0.56, -0.11)]	<.001
Week 8	116	4.0 (2.72)		227	3.0 (2.49)			
Week 8 chg	116	-3.0 (2.48)	-2.92 (0.20)	227	-3.9 (2.52)	-3.87 (0.14)	-0.95 (-1.43, -0.47) [-0.38 (-0.60, -0.15)]	<.001
Week 9	116	3.9 (2.78)		235	2.8 (2.36)			
Week 9 chg	116	-3.1 (2.48)	-3.03 (0.20)	235	-4.1 (2.49)	-4.07 (0.14)	-1.04 (-1.52, -0.56) [-0.42 (-0.64, -0.19)]	<.001
Week 10	114	3.9 (2.81)		235	2.7 (2.40)			
Week 10 chg	114	-3.1 (2.56)	-3.09 (0.20)	235	-4.1 (2.59)	-4.11 (0.14)	-1.02 (-1.50, -0.54) [-0.40 (-0.62, -0.17)]	<.001
Week 11	115	3.8 (2.71)		231	2.6 (2.33)			
Week 11 chg	115	-3.2 (2.54)	-3.10 (0.20)	231	-4.2 (2.58)	-4.22 (0.14)	-1.12 (-1.60, -0.64) [-0.44 (-0.66, -0.21)]	<.001
Week 12	115	3.8 (2.78)		234	2.7 (2.32)			
Week 12 chg	115	-3.2 (2.59)	-3.10 (0.20)	234	-4.2 (2.61)	-4.19 (0.14)	-1.09 (-1.57, -0.61) [-0.42 (-0.64, -0.19)]	<.001
Week 13	115	3.9 (2.80)		233	2.5 (2.33)			
Week 13 chg	115	-3.2 (2.52)	-3.16 (0.20)	233	-4.4 (2.66)	-4.39 (0.14)	-1.24 (-1.72, -0.75) [-0.47 (-0.70, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0248
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 1.7.295.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	116	3.8 (2.86)		223	2.5 (2.29)		
Week 14 chg	116	-3.2 (2.61)	-3.14 (0.20)	223	-4.3 (2.69)	-4.33 (0.14)	-1.20 (-1.68, -0.72) <.001 [-0.45 (-0.68, -0.22)]
Week 15	114	3.8 (2.87)		225	2.4 (2.27)		
Week 15 chg	114	-3.2 (2.56)	-3.14 (0.20)	225	-4.4 (2.64)	-4.39 (0.14)	-1.25 (-1.73, -0.77) <.001 [-0.48 (-0.71, -0.25)]
Week 16	112	3.7 (2.86)		226	2.4 (2.25)		
Week 16 chg	112	-3.3 (2.59)	-3.19 (0.20)	226	-4.4 (2.62)	-4.39 (0.14)	-1.21 (-1.69, -0.72) <.001 [-0.46 (-0.69, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0248
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 1.7.295.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	66	66 6.8 (2.23)		136	136 6.7 (2.19)			
Week 1		66 5.3 (2.55)			135 5.4 (2.33)			
Week 1 chg		66 -1.6 (1.93)	-1.53 (0.27)		135 -1.3 (1.54)	-1.25 (0.19)	0.29 (-0.36, 0.94) [0.17 (-0.12, 0.47)]	0.381
Week 2		66 4.8 (2.75)			131 4.6 (2.52)			
Week 2 chg		66 -2.0 (2.40)	-2.00 (0.27)		131 -2.0 (2.00)	-1.98 (0.19)	0.03 (-0.62, 0.68) [0.01 (-0.28, 0.31)]	0.932
Week 3		66 4.5 (2.58)			130 4.1 (2.53)			
Week 3 chg		66 -2.3 (2.34)	-2.23 (0.27)		130 -2.5 (2.23)	-2.53 (0.19)	-0.30 (-0.95, 0.35) [-0.13 (-0.43, 0.17)]	0.367
Week 4		63 4.0 (2.62)			132 3.9 (2.52)			
Week 4 chg		63 -2.7 (2.41)	-2.62 (0.27)		132 -2.8 (2.31)	-2.77 (0.19)	-0.15 (-0.80, 0.50) [-0.07 (-0.37, 0.23)]	0.643
Week 5		62 3.7 (2.60)			129 3.5 (2.46)			
Week 5 chg		62 -3.1 (2.50)	-3.00 (0.27)		129 -3.2 (2.37)	-3.17 (0.19)	-0.17 (-0.82, 0.48) [-0.07 (-0.37, 0.23)]	0.610
Week 6		65 3.7 (2.63)			127 3.2 (2.39)			
Week 6 chg		65 -3.1 (2.60)	-2.96 (0.27)		127 -3.4 (2.44)	-3.30 (0.19)	-0.34 (-0.99, 0.31) [-0.14 (-0.44, 0.16)]	0.298
Week 7		62 3.4 (2.64)			125 3.1 (2.39)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0248
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 1.7.295.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	62	-3.4 (2.63)	-3.24 (0.27)	125	-3.5 (2.52)	-3.48 (0.19)	-0.24 (-0.89, 0.41) 0.472 [-0.09 (-0.40, 0.21)]
Week 8	62	3.4 (2.51)		123	3.1 (2.49)		
Week 8 chg	62	-3.4 (2.59)	-3.21 (0.27)	123	-3.5 (2.58)	-3.54 (0.19)	-0.33 (-0.98, 0.33) 0.327 [-0.13 (-0.43, 0.18)]
Week 9	63	3.3 (2.55)		125	2.8 (2.31)		
Week 9 chg	63	-3.5 (2.60)	-3.35 (0.27)	125	-3.8 (2.53)	-3.85 (0.19)	-0.50 (-1.16, 0.15) 0.130 [-0.20 (-0.50, 0.11)]
Week 10	60	3.3 (2.59)		126	2.8 (2.40)		
Week 10 chg	60	-3.4 (2.67)	-3.42 (0.27)	126	-3.8 (2.55)	-3.83 (0.19)	-0.42 (-1.07, 0.24) 0.211 [-0.16 (-0.47, 0.15)]
Week 11	61	3.2 (2.46)		126	2.7 (2.23)		
Week 11 chg	61	-3.5 (2.63)	-3.37 (0.27)	126	-3.8 (2.59)	-3.91 (0.19)	-0.54 (-1.20, 0.11) 0.103 [-0.21 (-0.52, 0.10)]
Week 12	61	3.2 (2.54)		124	2.7 (2.27)		
Week 12 chg	61	-3.5 (2.66)	-3.38 (0.27)	124	-3.9 (2.62)	-3.99 (0.19)	-0.62 (-1.27, 0.04) 0.065 [-0.23 (-0.54, 0.07)]
Week 13	60	3.4 (2.60)		123	2.5 (2.27)		
Week 13 chg	60	-3.4 (2.61)	-3.34 (0.27)	123	-4.1 (2.70)	-4.16 (0.19)	-0.83 (-1.48, -0.17) 0.014 [-0.31 (-0.62, 0.00)]
Week 14	62	3.2 (2.76)		122	2.7 (2.33)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0248
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.

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Table 1.7.295.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	62	-3.5 (2.72)	-3.37 (0.27)	122	-3.9 (2.77)	-4.04 (0.19)	-0.67 (-1.32, -0.01) 0.045 [-0.24 (-0.55, 0.06)]
Week 15	59	3.3 (2.68)		123	2.6 (2.37)		
Week 15 chg	59	-3.4 (2.65)	-3.34 (0.27)	123	-4.1 (2.73)	-4.10 (0.19)	-0.76 (-1.41, -0.10) 0.024 [-0.28 (-0.59, 0.03)]
Week 16	60	3.2 (2.70)		124	2.5 (2.30)		
Week 16 chg	60	-3.6 (2.67)	-3.44 (0.27)	124	-4.0 (2.71)	-4.15 (0.19)	-0.71 (-1.36, -0.05) 0.035 [-0.26 (-0.57, 0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0248
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 1.7.295.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	60	60 7.4 (2.14)		116	115 7.2 (2.02)		
Week 1		59 6.1 (2.14)			113 5.2 (2.34)		
Week 1 chg		59 -1.3 (1.16)	-1.22 (0.29)		113 -1.9 (1.78)	-1.93 (0.21)	-0.71 (-1.41, -0.01) 0.045 [-0.45 (-0.76, -0.13)]
Week 2		60 5.5 (2.51)			114 4.4 (2.58)		
Week 2 chg		60 -1.8 (1.86)	-1.79 (0.29)		114 -2.8 (2.34)	-2.78 (0.21)	-1.00 (-1.69, -0.30) 0.005 [-0.45 (-0.77, -0.14)]
Week 3		59 5.4 (2.59)			113 3.8 (2.61)		
Week 3 chg		59 -2.0 (1.97)	-1.99 (0.29)		113 -3.3 (2.39)	-3.34 (0.21)	-1.36 (-2.05, -0.66) <.001 [-0.60 (-0.92, -0.28)]
Week 4		57 5.2 (2.67)			112 3.6 (2.68)		
Week 4 chg		57 -2.2 (2.06)	-2.25 (0.29)		112 -3.6 (2.47)	-3.59 (0.21)	-1.34 (-2.04, -0.64) <.001 [-0.57 (-0.90, -0.25)]
Week 5		56 5.0 (2.71)			109 3.3 (2.56)		
Week 5 chg		56 -2.4 (2.08)	-2.37 (0.29)		109 -3.9 (2.39)	-3.85 (0.21)	-1.48 (-2.18, -0.78) <.001 [-0.65 (-0.98, -0.32)]
Week 6		57 5.0 (2.77)			112 3.2 (2.63)		
Week 6 chg		57 -2.4 (2.17)	-2.42 (0.29)		112 -4.0 (2.61)	-3.97 (0.21)	-1.55 (-2.25, -0.85) <.001 [-0.63 (-0.95, -0.30)]
Week 7		54 4.6 (2.77)			106 3.0 (2.56)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0248
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 1.7.295.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	54	-2.7 (2.30)	-2.66 (0.29)	106	-4.2 (2.47)	-4.19 (0.21)	-1.54 (-2.24, -0.83) <.001 [-0.64 (-0.97, -0.30)]
Week 8	54	4.7 (2.78)		104	2.8 (2.50)		
Week 8 chg	54	-2.6 (2.31)	-2.60 (0.29)	104	-4.3 (2.38)	-4.26 (0.21)	-1.66 (-2.36, -0.95) <.001 [-0.70 (-1.04, -0.37)]
Week 9	53	4.7 (2.88)		110	2.8 (2.43)		
Week 9 chg	53	-2.6 (2.25)	-2.65 (0.29)	110	-4.4 (2.41)	-4.32 (0.21)	-1.67 (-2.37, -0.97) <.001 [-0.71 (-1.04, -0.37)]
Week 10	54	4.6 (2.90)		109	2.7 (2.40)		
Week 10 chg	54	-2.7 (2.37)	-2.73 (0.29)	109	-4.5 (2.60)	-4.45 (0.21)	-1.72 (-2.42, -1.01) <.001 [-0.68 (-1.01, -0.34)]
Week 11	54	4.4 (2.85)		105	2.5 (2.44)		
Week 11 chg	54	-2.8 (2.40)	-2.81 (0.29)	105	-4.7 (2.50)	-4.59 (0.21)	-1.79 (-2.49, -1.08) <.001 [-0.72 (-1.06, -0.39)]
Week 12	54	4.5 (2.92)		110	2.7 (2.39)		
Week 12 chg	54	-2.8 (2.48)	-2.80 (0.29)	110	-4.5 (2.57)	-4.44 (0.21)	-1.64 (-2.34, -0.94) <.001 [-0.64 (-0.98, -0.31)]
Week 13	55	4.4 (2.93)		110	2.5 (2.40)		
Week 13 chg	55	-3.0 (2.41)	-2.96 (0.29)	110	-4.7 (2.58)	-4.67 (0.21)	-1.71 (-2.41, -1.01) <.001 [-0.68 (-1.01, -0.35)]
Week 14	54	4.4 (2.87)		101	2.3 (2.23)		

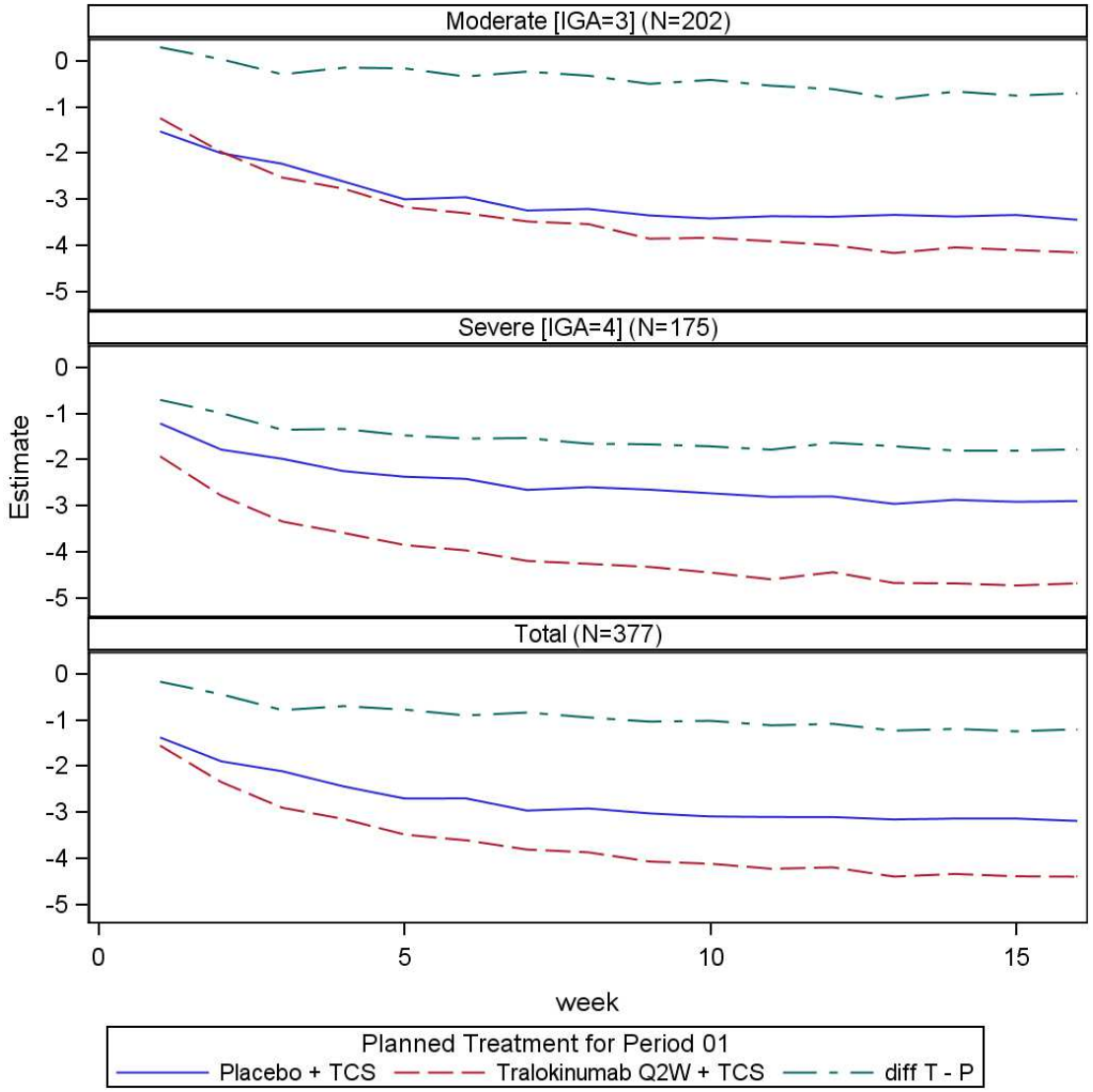
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0248
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.7.295.3.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	54	-2.9 (2.45)	-2.87 (0.29)	101	-4.8 (2.50)	-4.68 (0.21)	-1.81 (-2.51, -1.10) [-0.73 (-1.07, -0.39)]	<.001
Week 15	55	4.4 (2.97)		102	2.3 (2.14)			
Week 15 chg	55	-2.9 (2.45)	-2.91 (0.29)	102	-4.9 (2.47)	-4.72 (0.21)	-1.81 (-2.51, -1.11) [-0.73 (-1.07, -0.40)]	<.001
Week 16	52	4.3 (2.95)		102	2.3 (2.20)			
Week 16 chg	52	-2.9 (2.47)	-2.90 (0.29)	102	-4.8 (2.46)	-4.68 (0.21)	-1.78 (-2.49, -1.07) [-0.72 (-1.07, -0.38)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0248
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 1.7.295.3.2: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy estimand, LP0162-1339, 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 1.7.297.3.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	126	126 68.9 (13.19)		252	252 67.0 (13.26)		
Week 2		124 51.4 (17.14)			250 46.5 (16.69)		
Week 2 chg		124 -17.3 (16.94)	-16.83 (1.52)		250 -20.5 (14.91)	-20.64 (1.07)	-3.81 (-7.47, -0.15) 0.042 [-0.24 (-0.46, -0.03)]
Week 4		126 46.6 (20.16)			246 40.1 (16.71)		
Week 4 chg		126 -22.3 (19.12)	-21.68 (1.52)		246 -26.9 (15.62)	-26.91 (1.08)	-5.23 (-8.89, -1.57) 0.005 [-0.31 (-0.53, -0.09)]
Week 6		125 43.6 (20.47)			247 35.7 (16.22)		
Week 6 chg		125 -25.2 (18.79)	-24.72 (1.52)		247 -31.2 (15.78)	-31.15 (1.08)	-6.43 (-10.1, -2.76) <.001 [-0.38 (-0.60, -0.16)]
Week 8		122 41.9 (19.17)			243 32.7 (16.17)		
Week 8 chg		122 -26.8 (17.76)	-25.99 (1.53)		243 -34.2 (16.42)	-34.13 (1.08)	-8.15 (-11.8, -4.47) <.001 [-0.48 (-0.70, -0.26)]
Week 10		118 40.4 (20.53)			236 30.2 (16.85)		
Week 10 chg		118 -28.0 (19.22)	-27.39 (1.54)		236 -36.5 (18.20)	-36.38 (1.09)	-8.99 (-12.7, -5.29) <.001 [-0.48 (-0.71, -0.26)]
Week 12		119 39.6 (21.65)			238 29.4 (17.23)		
Week 12 chg		119 -28.8 (20.95)	-28.05 (1.53)		238 -37.6 (18.51)	-37.68 (1.08)	-9.63 (-13.3, -5.94) <.001 [-0.50 (-0.72, -0.27)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.297.3.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		118 38.8 (22.39)			235 28.5 (18.20)		
Week 14 chg		118 -29.6 (21.97)	-28.76 (1.54)		235 -38.4 (18.95)	-38.28 (1.09)	-9.52 (-13.2, -5.82) <.001 [-0.48 (-0.70, -0.25)]
Week 16		122 40.9 (23.52)			241 29.4 (18.62)		
Week 16 chg		122 -27.7 (22.50)	-26.84 (1.53)		241 -37.4 (19.31)	-37.43 (1.08)	-10.59 (-14.3, -6.91) <.001 [-0.52 (-0.74, -0.30)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.297.3.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	66	66 62.4 (9.82)		136	136 59.8 (9.82)		
Week 2		66 45.7 (14.08)			135 43.5 (15.18)		
Week 2 chg		66 -16.7 (17.76)	-15.72 (1.98)		135 -16.4 (13.26)	-16.69 (1.37)	-0.97 (-5.71, 3.78) 0.689 [-0.07 (-0.36, 0.23)]
Week 4		66 39.0 (15.44)			130 37.3 (15.26)		
Week 4 chg		66 -23.4 (19.11)	-22.30 (1.98)		130 -22.2 (14.02)	-22.47 (1.39)	-0.17 (-4.93, 4.60) 0.946 [-0.01 (-0.31, 0.29)]
Week 6		66 35.0 (16.91)			132 32.9 (14.85)		
Week 6 chg		66 -27.4 (19.46)	-26.24 (1.98)		132 -26.8 (14.54)	-27.07 (1.38)	-0.84 (-5.59, 3.92) 0.730 [-0.05 (-0.35, 0.24)]
Week 8		64 34.8 (14.76)			130 30.1 (15.19)		
Week 8 chg		64 -27.7 (17.80)	-25.96 (1.99)		130 -29.5 (15.41)	-29.84 (1.39)	-3.88 (-8.66, 0.91) 0.112 [-0.24 (-0.54, 0.06)]
Week 10		63 32.3 (16.21)			128 28.4 (15.76)		
Week 10 chg		63 -29.9 (19.13)	-28.45 (1.99)		128 -31.3 (16.29)	-31.59 (1.39)	-3.14 (-7.94, 1.66) 0.199 [-0.18 (-0.48, 0.12)]
Week 12		65 31.4 (17.47)			128 25.9 (15.85)		
Week 12 chg		65 -30.9 (20.66)	-29.16 (1.98)		128 -33.7 (16.96)	-34.36 (1.39)	-5.21 (-9.98, -0.43) 0.033 [-0.28 (-0.58, 0.02)]
Week 14		63 29.8 (18.55)			125 26.3 (18.05)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.297.3.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	63	-32.7 (21.76)	-30.66 (2.00)	125	-33.1 (18.41)	-33.43 (1.40)	-2.77 (-7.58, 2.04) 0.258 [-0.14 (-0.44, 0.16)]
Week 16	66	31.9 (18.45)		130	26.6 (17.70)		
Week 16 chg	66	-30.6 (21.09)	-29.14 (1.98)	130	-33.0 (18.25)	-33.33 (1.39)	-4.19 (-8.96, 0.57) 0.084 [-0.22 (-0.51, 0.08)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.297.3.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	60	60 75.9 (12.83)		116	116 75.3 (11.84)		
Week 2		58 57.8 (18.11)			115 50.1 (17.71)		
Week 2 chg		58 -17.9 (16.08)	-18.14 (2.26)		115 -25.3 (15.35)	-25.30 (1.62)	-7.16 (-12.6, -1.69) 0.010 [-0.46 (-0.78, -0.14)]
Week 4		60 55.0 (21.50)			116 43.1 (17.77)		
Week 4 chg		60 -21.0 (19.21)	-20.86 (2.25)		116 -32.2 (15.69)	-32.18 (1.62)	-11.32 (-16.8, -5.88) <.001 [-0.67 (-0.99, -0.35)]
Week 6		59 53.2 (19.90)			115 39.0 (17.13)		
Week 6 chg		59 -22.6 (17.83)	-22.85 (2.25)		115 -36.2 (15.71)	-36.03 (1.62)	-13.18 (-18.6, -7.72) <.001 [-0.80 (-1.13, -0.48)]
Week 8		58 49.8 (20.46)			113 35.6 (16.80)		
Week 8 chg		58 -25.9 (17.82)	-25.82 (2.26)		113 -39.6 (15.92)	-39.29 (1.62)	-13.47 (-18.9, -7.99) <.001 [-0.81 (-1.14, -0.48)]
Week 10		55 49.6 (21.17)			108 32.4 (17.89)		
Week 10 chg		55 -25.9 (19.28)	-26.01 (2.28)		108 -42.7 (18.46)	-42.11 (1.64)	-16.10 (-21.6, -10.6) <.001 [-0.86 (-1.20, -0.52)]
Week 12		54 49.5 (22.20)			110 33.4 (17.95)		
Week 12 chg		54 -26.2 (21.20)	-26.37 (2.29)		110 -42.1 (19.28)	-41.77 (1.63)	-15.40 (-20.9, -9.87) <.001 [-0.77 (-1.11, -0.44)]
Week 14		55 49.1 (22.08)			110 31.0 (18.14)		

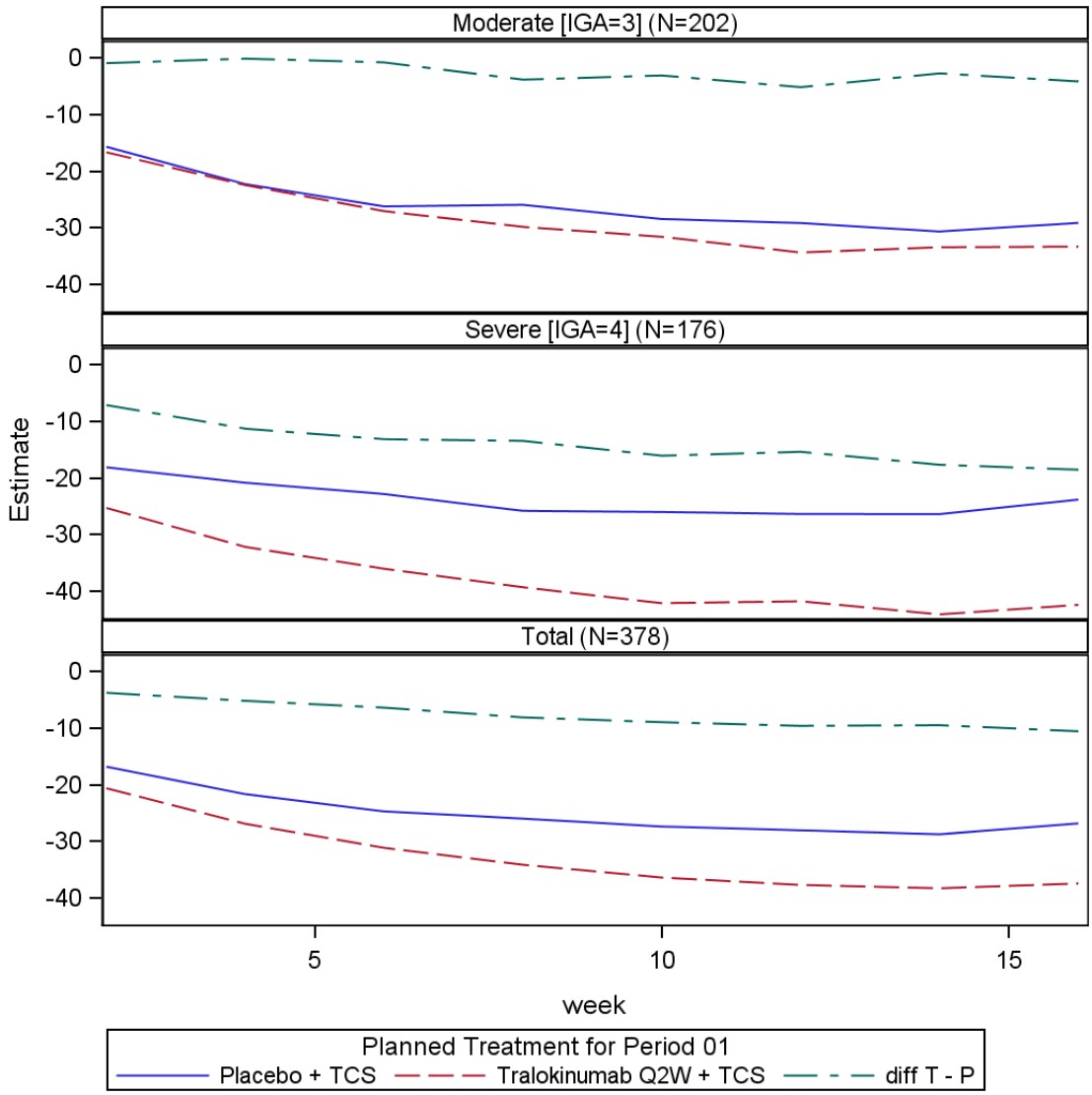
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.7.297.3.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	55	-26.2 (21.89)	-26.39 (2.28)	110	-44.4 (17.79)	-44.08 (1.63)	-17.69 (-23.2, -12.2) [-0.92 (-1.26, -0.58)]	<.001
Week 16	56	51.6 (24.50)		111	32.7 (19.20)			
Week 16 chg	56	-24.3 (23.80)	-23.84 (2.27)	111	-42.5 (19.36)	-42.40 (1.63)	-18.56 (-24.1, -13.1) [-0.89 (-1.22, -0.55)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: <.0001
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 1.7.297.3.2: Total, Disease severity (IGA), change in SCORAD, Treatment policy estimand, LP0162-1339, 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 1.7.299.3.1: Total, Disease severity (IGA), change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score										
Total										
Baseline	126	125	17.2 (7.15)		252	250	17.6 (7.07)			
Week 2		121	9.8 (7.21)			249	8.6 (6.22)			
Week 2 chg		121	-7.3 (6.72)	-7.51 (0.53)		249	-9.0 (7.25)	-8.97 (0.37)	-1.46 (-2.73, -0.19) [-0.21 (-0.42, 0.01)]	0.024
Week 4		122	9.1 (7.39)			245	7.4 (6.28)			
Week 4 chg		122	-8.1 (7.14)	-8.21 (0.53)		245	-10.2 (7.54)	-10.08 (0.37)	-1.87 (-3.14, -0.60) [-0.25 (-0.47, -0.03)]	0.004
Week 6		123	8.4 (6.88)			242	6.3 (5.75)			
Week 6 chg		123	-8.8 (6.70)	-9.03 (0.53)		242	-11.3 (7.41)	-11.01 (0.37)	-1.99 (-3.25, -0.72) [-0.28 (-0.49, -0.06)]	0.002
Week 8		120	8.1 (6.80)			239	6.2 (5.71)			
Week 8 chg		120	-9.1 (7.09)	-9.21 (0.53)		239	-11.6 (7.90)	-11.35 (0.37)	-2.14 (-3.41, -0.87) [-0.28 (-0.50, -0.06)]	0.001
Week 12		116	7.9 (7.06)			227	5.7 (5.50)			
Week 12 chg		116	-9.0 (7.22)	-9.18 (0.53)		227	-11.9 (7.98)	-11.80 (0.38)	-2.62 (-3.90, -1.34) [-0.34 (-0.56, -0.11)]	<.001
Week 16		119	8.4 (7.30)			237	5.7 (6.02)			
Week 16 chg		119	-8.8 (7.09)	-9.07 (0.53)		237	-11.8 (7.57)	-11.70 (0.38)	-2.64 (-3.91, -1.36) [-0.36 (-0.58, -0.13)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5074
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 1.7.299.3.1: Total, Disease severity (IGA), change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]										
Baseline	66	65	16.1 (7.29)		136	135	16.2 (7.12)			
Week 2		63	9.1 (6.94)			135	8.6 (6.45)			
Week 2 chg		63	-7.0 (6.78)	-7.13 (0.70)		135	-7.6 (7.02)	-7.61 (0.49)	-0.49 (-2.17, 1.20) [-0.07 (-0.37, 0.23)]	0.570
Week 4		64	8.0 (6.26)			130	7.3 (6.31)			
Week 4 chg		64	-8.1 (7.26)	-8.28 (0.70)		130	-8.9 (7.24)	-8.81 (0.49)	-0.52 (-2.21, 1.16) [-0.07 (-0.37, 0.23)]	0.542
Week 6		65	7.6 (6.56)			129	6.2 (5.51)			
Week 6 chg		65	-8.5 (7.09)	-8.53 (0.70)		129	-10.0 (7.25)	-9.79 (0.49)	-1.26 (-2.94, 0.42) [-0.18 (-0.47, 0.12)]	0.141
Week 8		63	7.3 (5.98)			128	6.0 (5.81)			
Week 8 chg		63	-8.9 (7.47)	-8.78 (0.70)		128	-10.3 (7.94)	-10.17 (0.49)	-1.39 (-3.08, 0.30) [-0.18 (-0.48, 0.12)]	0.107
Week 12		63	7.6 (7.00)			123	5.8 (5.70)			
Week 12 chg		63	-8.6 (7.18)	-8.43 (0.70)		123	-10.4 (7.82)	-10.46 (0.50)	-2.03 (-3.72, -0.34) [-0.27 (-0.57, 0.04)]	0.019
Week 16		62	7.5 (6.44)			127	5.4 (6.01)			
Week 16 chg		62	-8.8 (6.90)	-8.91 (0.71)		127	-10.7 (7.34)	-10.67 (0.49)	-1.76 (-3.46, -0.07) [-0.24 (-0.55, 0.06)]	0.042

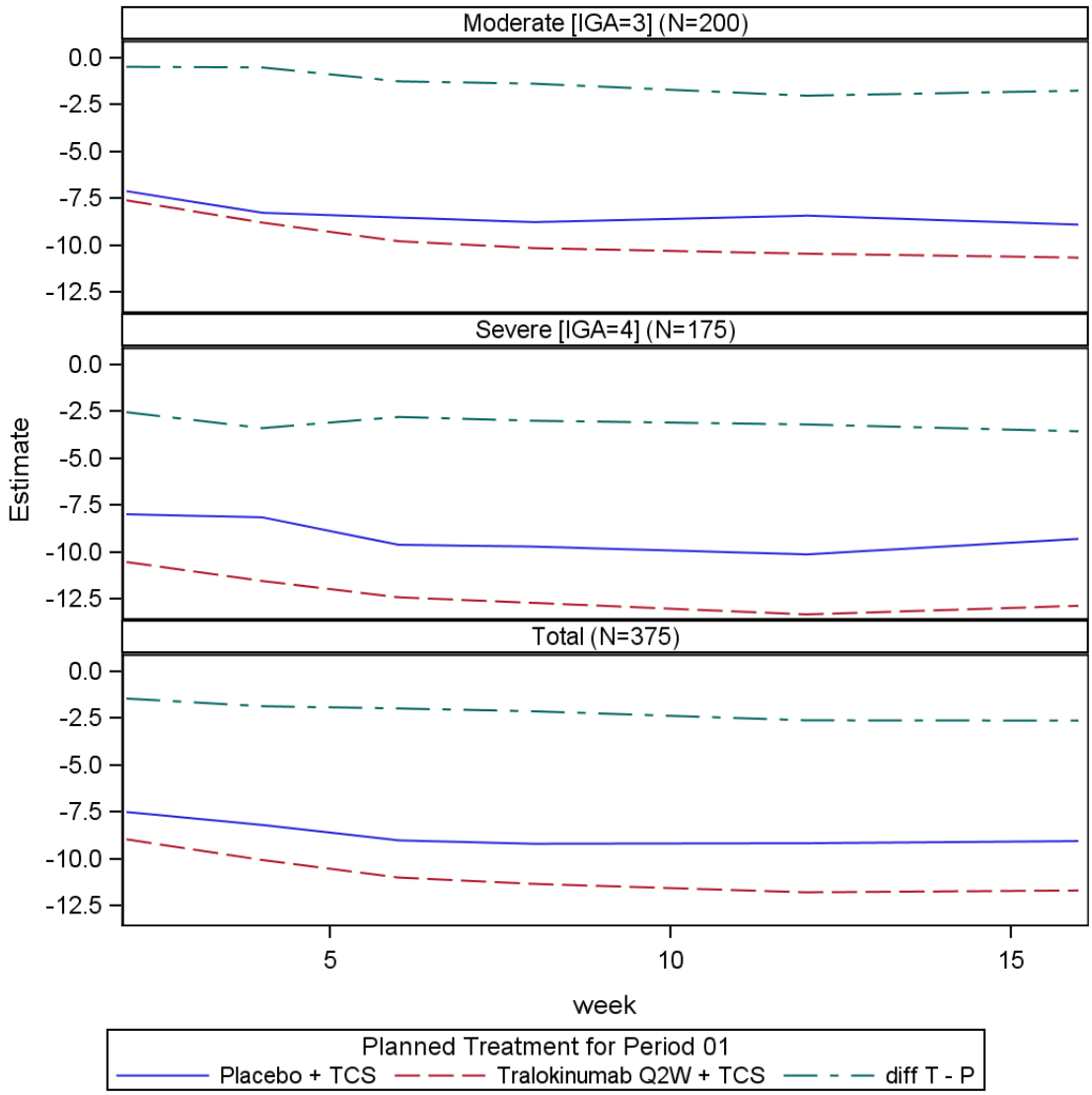
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5074
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.7.299.3.1: Total, Disease severity (IGA), change in DLQI, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	60	60 18.4 (6.87)		116	115 19.2 (6.68)		
Week 2		58 10.5 (7.49)			114 8.5 (5.98)		
Week 2 chg		58 -7.7 (6.69)	-8.00 (0.78)		114 -10.8 (7.18)	-10.55 (0.56)	-2.55 (-4.44, -0.66) 0.008 [-0.36 (-0.68, -0.04)]
Week 4		58 10.4 (8.32)			115 7.5 (6.28)		
Week 4 chg		58 -8.1 (7.06)	-8.16 (0.78)		115 -11.8 (7.62)	-11.56 (0.56)	-3.40 (-5.29, -1.51) <.001 [-0.46 (-0.78, -0.14)]
Week 6		58 9.3 (7.17)			113 6.6 (6.04)		
Week 6 chg		58 -9.2 (6.26)	-9.63 (0.78)		113 -12.7 (7.36)	-12.43 (0.56)	-2.80 (-4.69, -0.91) 0.004 [-0.40 (-0.72, -0.08)]
Week 8		57 9.0 (7.55)			111 6.3 (5.61)		
Week 8 chg		57 -9.4 (6.70)	-9.73 (0.78)		111 -13.1 (7.61)	-12.73 (0.56)	-3.00 (-4.90, -1.11) 0.002 [-0.41 (-0.73, -0.09)]
Week 12		53 8.3 (7.17)			104 5.5 (5.28)		
Week 12 chg		53 -9.4 (7.30)	-10.14 (0.79)		104 -13.6 (7.88)	-13.34 (0.57)	-3.20 (-5.13, -1.28) 0.001 [-0.42 (-0.75, -0.08)]
Week 16		57 9.3 (8.09)			110 6.1 (6.03)		
Week 16 chg		57 -8.7 (7.36)	-9.31 (0.78)		110 -13.1 (7.67)	-12.89 (0.56)	-3.57 (-5.47, -1.67) <.001 [-0.47 (-0.80, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5074
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 1.7.299.3.2: Total, Disease severity (IGA), change in DLQI, Treatment policy estimand, LP0162-1339, 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 1.7.300.3.1: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total										
Total										
Baseline	126	124	22.4 (5.63)		252	250	22.3 (5.09)			
Week 2		120	16.2 (7.55)			248	14.4 (6.85)			
Week 2 chg		120	-6.1 (6.67)	-6.14 (0.61)		248	-7.8 (6.57)	-7.88 (0.42)	-1.74 (-3.19, -0.29) [-0.26 (-0.48, -0.04)]	0.019
Week 4		121	15.5 (7.82)			244	12.5 (6.95)			
Week 4 chg		121	-6.8 (7.00)	-6.89 (0.60)		244	-9.8 (7.02)	-9.82 (0.43)	-2.94 (-4.39, -1.48) [-0.42 (-0.64, -0.20)]	<.001
Week 6		122	14.7 (7.89)			242	11.4 (6.75)			
Week 6 chg		122	-7.7 (7.44)	-7.68 (0.60)		242	-10.9 (6.87)	-10.80 (0.43)	-3.12 (-4.57, -1.66) [-0.44 (-0.66, -0.22)]	<.001
Week 8		119	14.6 (7.88)			239	11.2 (7.08)			
Week 8 chg		119	-7.7 (7.38)	-7.60 (0.61)		239	-11.1 (7.24)	-11.05 (0.43)	-3.45 (-4.91, -1.99) [-0.47 (-0.70, -0.25)]	<.001
Week 12		115	14.0 (8.12)			227	10.6 (6.62)			
Week 12 chg		115	-8.2 (7.71)	-7.99 (0.61)		227	-11.6 (6.72)	-11.65 (0.43)	-3.67 (-5.14, -2.20) [-0.52 (-0.75, -0.29)]	<.001
Week 16		118	14.7 (8.27)			237	10.5 (7.20)			
Week 16 chg		118	-7.8 (7.40)	-7.85 (0.61)		237	-11.7 (7.37)	-11.68 (0.43)	-3.83 (-5.28, -2.37) [-0.52 (-0.74, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2967
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 1.7.300.3.1: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]										
Baseline	66	64	21.2 (6.00)		136	135	20.6 (5.54)			
Week 2		62	14.9 (7.50)			135	13.9 (6.87)			
Week 2 chg		62	-6.2 (6.85)	-6.08 (0.81)		135	-6.8 (6.36)	-6.81 (0.55)	-0.73 (-2.66, 1.19) [-0.11 (-0.41, 0.19)]	0.455
Week 4		63	14.1 (7.02)			130	11.7 (7.12)			
Week 4 chg		63	-7.0 (6.62)	-6.90 (0.81)		130	-8.9 (7.05)	-8.96 (0.56)	-2.06 (-3.98, -0.13) [-0.30 (-0.60, 0.00)]	0.037
Week 6		64	13.1 (7.20)			129	10.7 (6.79)			
Week 6 chg		64	-8.1 (7.23)	-7.84 (0.80)		129	-9.8 (6.94)	-9.78 (0.56)	-1.94 (-3.86, -0.01) [-0.28 (-0.58, 0.03)]	0.048
Week 8		62	12.7 (6.66)			128	10.7 (7.41)			
Week 8 chg		62	-8.3 (6.93)	-8.03 (0.81)		128	-9.9 (7.53)	-9.99 (0.56)	-1.95 (-3.89, -0.02) [-0.27 (-0.57, 0.04)]	0.048
Week 12		62	12.2 (7.35)			123	9.8 (6.84)			
Week 12 chg		62	-8.8 (7.59)	-8.45 (0.81)		123	-10.8 (6.62)	-10.99 (0.56)	-2.54 (-4.48, -0.60) [-0.36 (-0.67, -0.06)]	0.010
Week 16		61	12.9 (7.20)			127	10.0 (7.45)			
Week 16 chg		61	-8.5 (6.81)	-8.42 (0.81)		127	-10.4 (7.12)	-10.56 (0.56)	-2.14 (-4.08, -0.20) [-0.30 (-0.61, 0.00)]	0.031

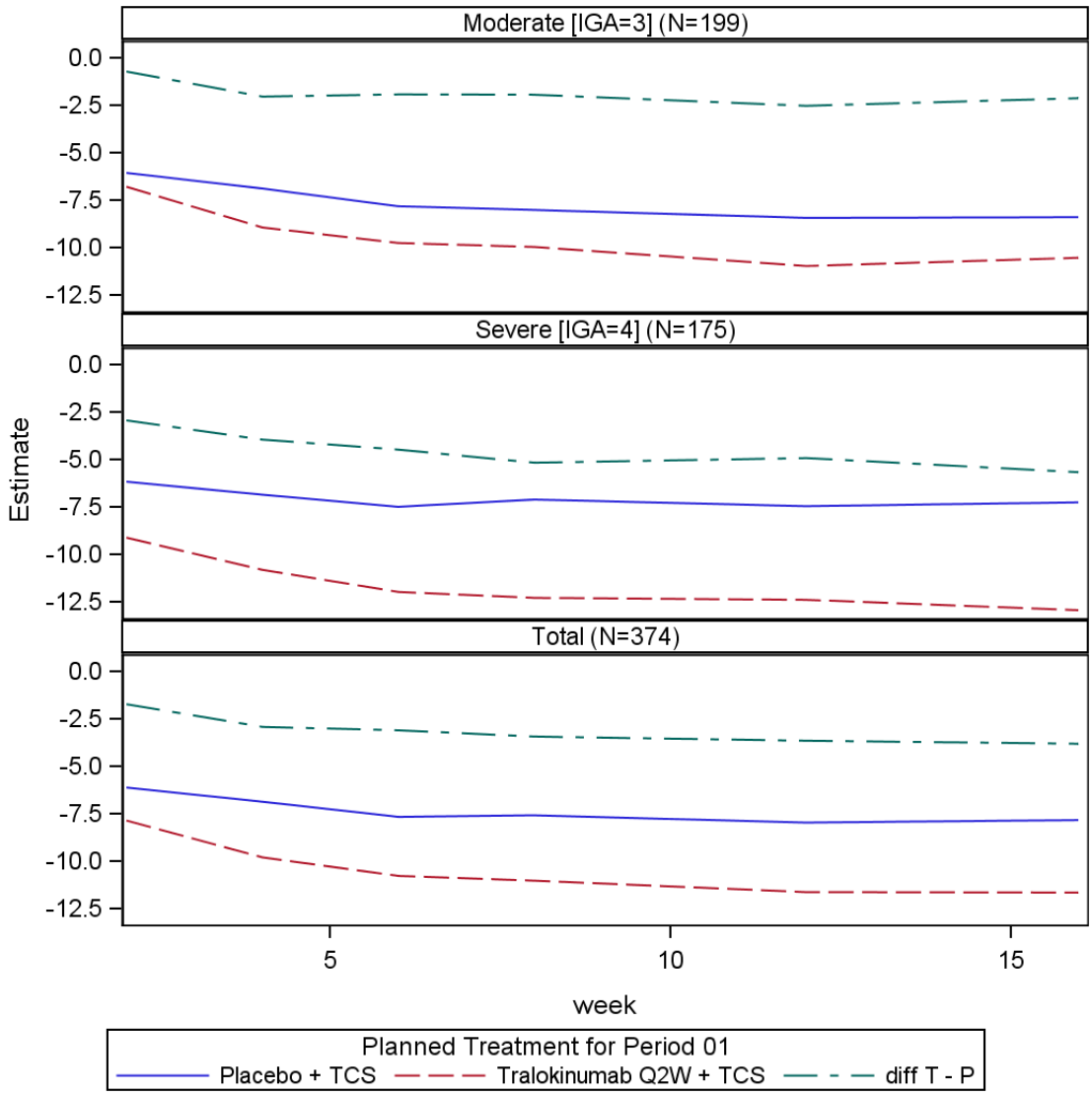
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2967
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected 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 1.7.300.3.1: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	60	60 23.6 (4.94)		116	115 24.2 (3.67)			
Week 2		58 17.6 (7.42)			113 15.1 (6.79)			
Week 2 chg		58 -6.0 (6.52)	-6.19 (0.90)		113 -9.1 (6.61)	-9.14 (0.65)	-2.95 (-5.13, -0.77) [-0.45 (-0.77, -0.13)]	0.008
Week 4		58 16.9 (8.42)			114 13.3 (6.67)			
Week 4 chg		58 -6.6 (7.44)	-6.87 (0.90)		114 -10.9 (6.85)	-10.84 (0.64)	-3.96 (-6.14, -1.79) [-0.56 (-0.88, -0.24)]	<.001
Week 6		58 16.4 (8.32)			113 12.1 (6.65)			
Week 6 chg		58 -7.2 (7.70)	-7.51 (0.90)		113 -12.1 (6.60)	-12.00 (0.65)	-4.49 (-6.67, -2.31) [-0.64 (-0.97, -0.32)]	<.001
Week 8		57 16.8 (8.59)			111 11.8 (6.67)			
Week 8 chg		57 -7.1 (7.85)	-7.13 (0.90)		111 -12.5 (6.67)	-12.32 (0.65)	-5.19 (-7.37, -3.00) [-0.73 (-1.06, -0.40)]	<.001
Week 12		53 16.1 (8.53)			104 11.5 (6.26)			
Week 12 chg		53 -7.5 (7.86)	-7.48 (0.91)		104 -12.7 (6.72)	-12.42 (0.65)	-4.94 (-7.15, -2.73) [-0.69 (-1.03, -0.35)]	<.001
Week 16		57 16.5 (8.97)			110 11.0 (6.91)			
Week 16 chg		57 -7.2 (7.99)	-7.28 (0.90)		110 -13.2 (7.41)	-12.97 (0.65)	-5.69 (-7.87, -3.50) [-0.75 (-1.08, -0.42)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2967
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 1.7.300.3.2: Total, Disease severity (IGA), change in POEM, Treatment policy estimand, LP0162-1339, 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 1.7.318.3.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss								
Total								
Baseline	126	126 6.9 (2.72)		252	252 6.5 (2.77)			
Week 2		124 4.4 (3.05)			250 3.7 (2.95)			
Week 2 chg		124 -2.5 (2.93)	-2.39 (0.24)		250 -2.8 (2.95)	-2.85 (0.17)	-0.46 (-1.03, 0.11)	0.115
							[-0.16 (-0.37, 0.06)]	
Week 4		126 3.7 (3.07)			246 3.1 (2.84)			
Week 4 chg		126 -3.1 (3.14)	-2.96 (0.24)		246 -3.3 (3.01)	-3.36 (0.17)	-0.40 (-0.97, 0.17)	0.167
							[-0.13 (-0.35, 0.08)]	
Week 6		125 3.4 (2.99)			247 2.7 (2.75)			
Week 6 chg		125 -3.5 (3.05)	-3.31 (0.24)		247 -3.7 (3.04)	-3.71 (0.17)	-0.40 (-0.97, 0.17)	0.166
							[-0.13 (-0.35, 0.08)]	
Week 8		122 3.4 (3.15)			243 2.5 (2.71)			
Week 8 chg		122 -3.4 (3.28)	-3.26 (0.24)		243 -3.9 (2.98)	-3.97 (0.17)	-0.71 (-1.28, -0.14)	0.015
							[-0.23 (-0.45, -0.01)]	
Week 10		118 3.2 (2.97)			236 2.3 (2.60)			
Week 10 chg		118 -3.6 (3.11)	-3.48 (0.24)		236 -4.1 (3.15)	-4.17 (0.17)	-0.70 (-1.27, -0.12)	0.017
							[-0.22 (-0.44, -0.00)]	
Week 12		119 3.1 (3.11)			238 2.2 (2.57)			
Week 12 chg		119 -3.7 (3.14)	-3.54 (0.24)		238 -4.2 (3.15)	-4.25 (0.17)	-0.71 (-1.29, -0.14)	0.015
							[-0.23 (-0.45, -0.01)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1461
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 VAS = Treatment*Week + [Baseline VAS]*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 1.7.318.3.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	118	3.0 (3.03)		235	2.0 (2.52)			
Week 14 chg	118	-3.8 (3.10)	-3.60 (0.24)	235	-4.4 (3.19)	-4.42 (0.17)	-0.82 (-1.39, -0.24) [-0.26 (-0.48, -0.04)]	0.005
Week 16	122	3.2 (3.24)		241	2.2 (2.68)			
Week 16 chg	122	-3.7 (3.20)	-3.46 (0.24)	241	-4.2 (3.34)	-4.27 (0.17)	-0.80 (-1.38, -0.23) [-0.24 (-0.46, -0.03)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1461
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 VAS = Treatment*Week + [Baseline VAS]*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 1.7.318.3.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	66	66 6.4 (2.82)		136	136 5.8 (2.85)		
Week 2		66 4.0 (3.03)			135 3.5 (2.92)		
Week 2 chg		66 -2.4 (3.06)	-2.19 (0.31)		135 -2.4 (2.94)	-2.40 (0.22)	-0.22 (-0.96, 0.53) 0.569 [-0.07 (-0.37, 0.22)]
Week 4		66 3.1 (2.82)			130 3.1 (2.76)		
Week 4 chg		66 -3.3 (3.27)	-3.03 (0.31)		130 -2.7 (3.03)	-2.78 (0.22)	0.25 (-0.50, 1.00) 0.511 [0.08 (-0.22, 0.38)]
Week 6		66 2.8 (2.71)			132 2.6 (2.55)		
Week 6 chg		66 -3.6 (3.13)	-3.36 (0.31)		132 -3.2 (3.06)	-3.23 (0.22)	0.13 (-0.62, 0.87) 0.740 [0.04 (-0.25, 0.34)]
Week 8		64 3.0 (2.86)			130 2.3 (2.58)		
Week 8 chg		64 -3.4 (3.25)	-3.18 (0.31)		130 -3.4 (3.03)	-3.53 (0.22)	-0.35 (-1.10, 0.40) 0.364 [-0.11 (-0.41, 0.19)]
Week 10		63 2.5 (2.54)			128 2.2 (2.48)		
Week 10 chg		63 -3.8 (3.25)	-3.58 (0.31)		128 -3.6 (3.20)	-3.68 (0.22)	-0.10 (-0.85, 0.66) 0.803 [-0.03 (-0.33, 0.27)]
Week 12		65 2.5 (2.76)			128 2.1 (2.39)		
Week 12 chg		65 -3.9 (3.24)	-3.57 (0.31)		128 -3.6 (3.20)	-3.80 (0.22)	-0.23 (-0.98, 0.52) 0.540 [-0.07 (-0.37, 0.23)]
Week 14		63 2.3 (2.65)			125 2.0 (2.52)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1461
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 VAS = Treatment*Week + [Baseline VAS]*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 1.7.318.3.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	63	-4.0 (3.16)	-3.72 (0.31)	125	-3.7 (3.31)	-3.79 (0.22)	-0.07 (-0.82, 0.68) [-0.02 (-0.32, 0.28)]	0.857
Week 16	66	2.6 (2.88)		130	2.0 (2.59)			
Week 16 chg	66	-3.8 (3.21)	-3.50 (0.31)	130	-3.7 (3.42)	-3.81 (0.22)	-0.31 (-1.06, 0.43) [-0.09 (-0.39, 0.20)]	0.409

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1461
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 VAS = Treatment*Week + [Baseline VAS]*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 1.7.318.3.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	60	60 7.4 (2.52)		116	116 7.2 (2.49)		
Week 2		58 4.8 (3.04)			115 3.8 (3.00)		
Week 2 chg		58 -2.6 (2.80)	-2.65 (0.36)		115 -3.3 (2.87)	-3.37 (0.25)	-0.72 (-1.58, 0.14) 0.101 [-0.25 (-0.57, 0.06)]
Week 4		60 4.5 (3.21)			116 3.2 (2.94)		
Week 4 chg		60 -3.0 (3.01)	-2.89 (0.35)		116 -4.0 (2.85)	-4.03 (0.25)	-1.15 (-2.01, -0.29) 0.009 [-0.39 (-0.71, -0.08)]
Week 6		59 4.1 (3.15)			115 2.9 (2.97)		
Week 6 chg		59 -3.3 (2.96)	-3.26 (0.36)		115 -4.3 (2.91)	-4.28 (0.26)	-1.02 (-1.88, -0.16) 0.020 [-0.35 (-0.66, -0.03)]
Week 8		58 4.0 (3.38)			113 2.7 (2.86)		
Week 8 chg		58 -3.4 (3.34)	-3.35 (0.36)		113 -4.5 (2.84)	-4.48 (0.26)	-1.14 (-2.00, -0.27) 0.010 [-0.38 (-0.70, -0.06)]
Week 10		55 4.0 (3.24)			108 2.4 (2.74)		
Week 10 chg		55 -3.4 (2.95)	-3.35 (0.36)		108 -4.8 (2.96)	-4.76 (0.26)	-1.41 (-2.28, -0.54) 0.002 [-0.48 (-0.81, -0.15)]
Week 12		54 3.9 (3.36)			110 2.4 (2.76)		
Week 12 chg		54 -3.5 (3.04)	-3.50 (0.36)		110 -4.8 (2.99)	-4.79 (0.26)	-1.29 (-2.16, -0.41) 0.004 [-0.43 (-0.76, -0.10)]
Week 14		55 3.8 (3.25)			110 2.0 (2.54)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1461
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 VAS = Treatment*Week + [Baseline VAS]*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.

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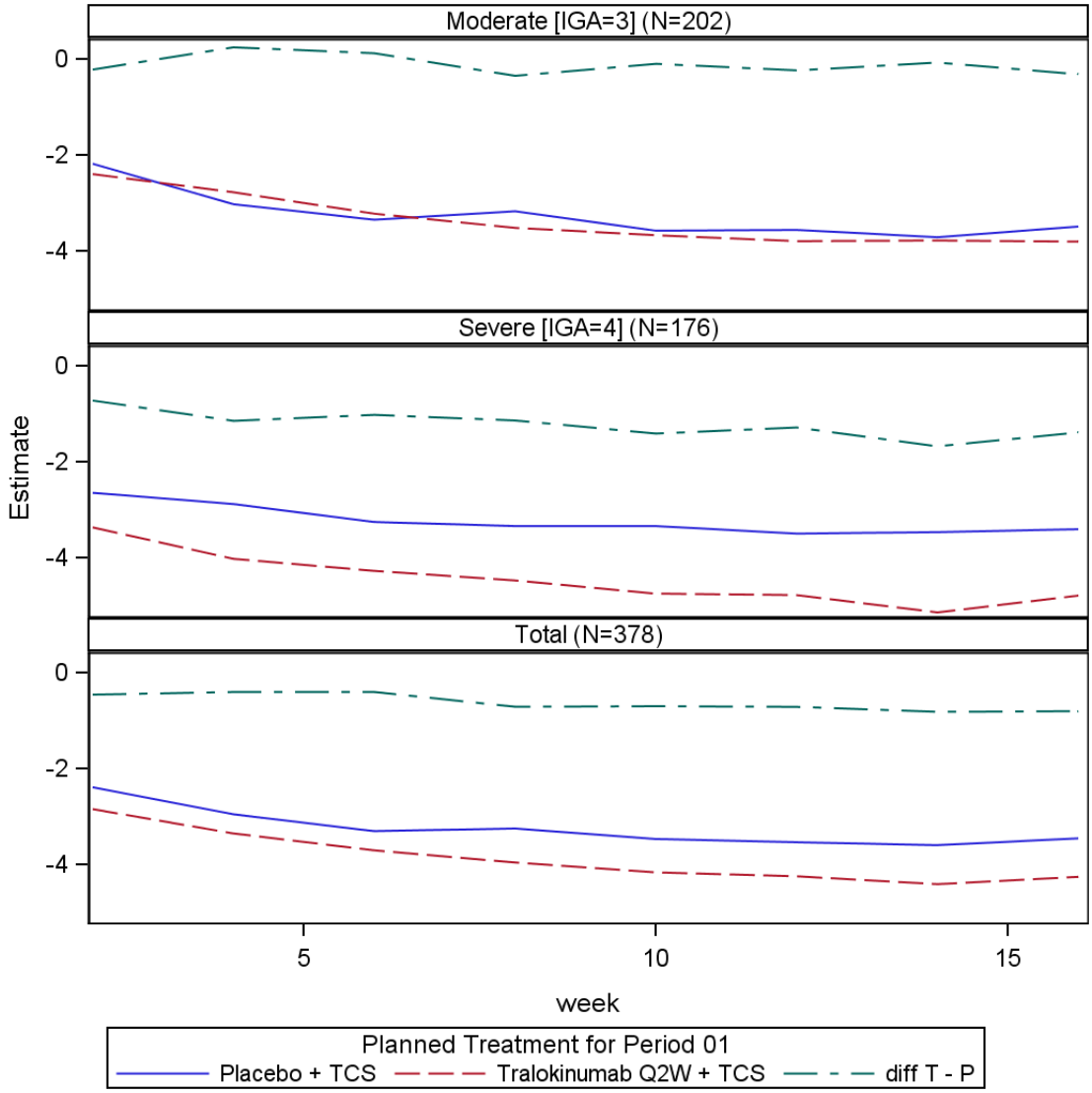
Table 1.7.318.3.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	55	-3.5 (3.04)	-3.47 (0.36)	110	-5.2 (2.86)	-5.15 (0.26)	-1.68 (-2.55, -0.81) [-0.58 (-0.91, -0.25)]	<.001
Week 16	56	3.9 (3.51)		111	2.4 (2.79)			
Week 16 chg	56	-3.5 (3.22)	-3.41 (0.36)	111	-4.7 (3.17)	-4.80 (0.26)	-1.39 (-2.26, -0.52) [-0.44 (-0.76, -0.11)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1461
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 VAS = Treatment*Week + [Baseline VAS]*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 1.7.318.3.2: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy estimand, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 1.7.319.3.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	126	125	59.4 (23.09)		252	250	59.1 (25.01)		
Week 4		122	70.1 (18.94)			249	74.1 (18.34)		
Week 4 chg		122	10.3 (18.72)	11.01 (1.54)		249	15.0 (21.76)	15.00 (1.09)	3.99 (0.28, 7.69) 0.035 [0.19 (-0.03, 0.41)]
Week 8		120	71.2 (20.22)			237	75.5 (18.26)		
Week 8 chg		120	12.1 (23.42)	12.22 (1.55)		237	16.4 (23.73)	16.03 (1.10)	3.81 (0.07, 7.55) 0.046 [0.16 (-0.06, 0.38)]
Week 12		116	72.3 (21.36)			227	75.1 (18.28)		
Week 12 chg		116	12.1 (23.53)	12.65 (1.57)		227	16.4 (23.72)	15.70 (1.12)	3.04 (-0.74, 6.83) 0.115 [0.13 (-0.10, 0.35)]
Week 16		116	71.5 (21.22)			232	75.8 (18.84)		
Week 16 chg		116	12.4 (22.66)	12.51 (1.57)		232	17.0 (24.19)	16.27 (1.11)	3.77 (-0.01, 7.55) 0.051 [0.16 (-0.06, 0.38)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5754
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 VAS = Treatment*Week + [Baseline VAS]*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 1.7.319.3.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]									
Baseline	66	65	66.0 (20.69)		136	135	64.4 (24.29)		
Week 4		64	71.8 (17.60)			135	76.2 (17.86)		
Week 4 chg		64	6.2 (15.28)	6.86 (1.98)		135	11.8 (18.75)	11.70 (1.37)	4.84 (0.11, 9.58) 0.045 [0.27 (-0.03, 0.57)]
Week 8		63	71.8 (21.26)			127	78.0 (17.43)		
Week 8 chg		63	6.3 (21.81)	6.87 (2.00)		127	13.6 (20.38)	13.23 (1.40)	6.37 (1.57, 11.16) 0.009 [0.31 (0.00, 0.61)]
Week 12		63	73.4 (21.99)			123	77.4 (18.25)		
Week 12 chg		63	7.3 (22.89)	8.00 (2.00)		123	13.9 (20.03)	13.13 (1.42)	5.13 (0.31, 9.94) 0.037 [0.24 (-0.06, 0.55)]
Week 16		60	74.5 (19.26)			124	77.3 (19.12)		
Week 16 chg		60	9.3 (21.83)	9.75 (2.03)		124	13.3 (21.49)	12.60 (1.41)	2.86 (-2.01, 7.72) 0.249 [0.13 (-0.18, 0.44)]

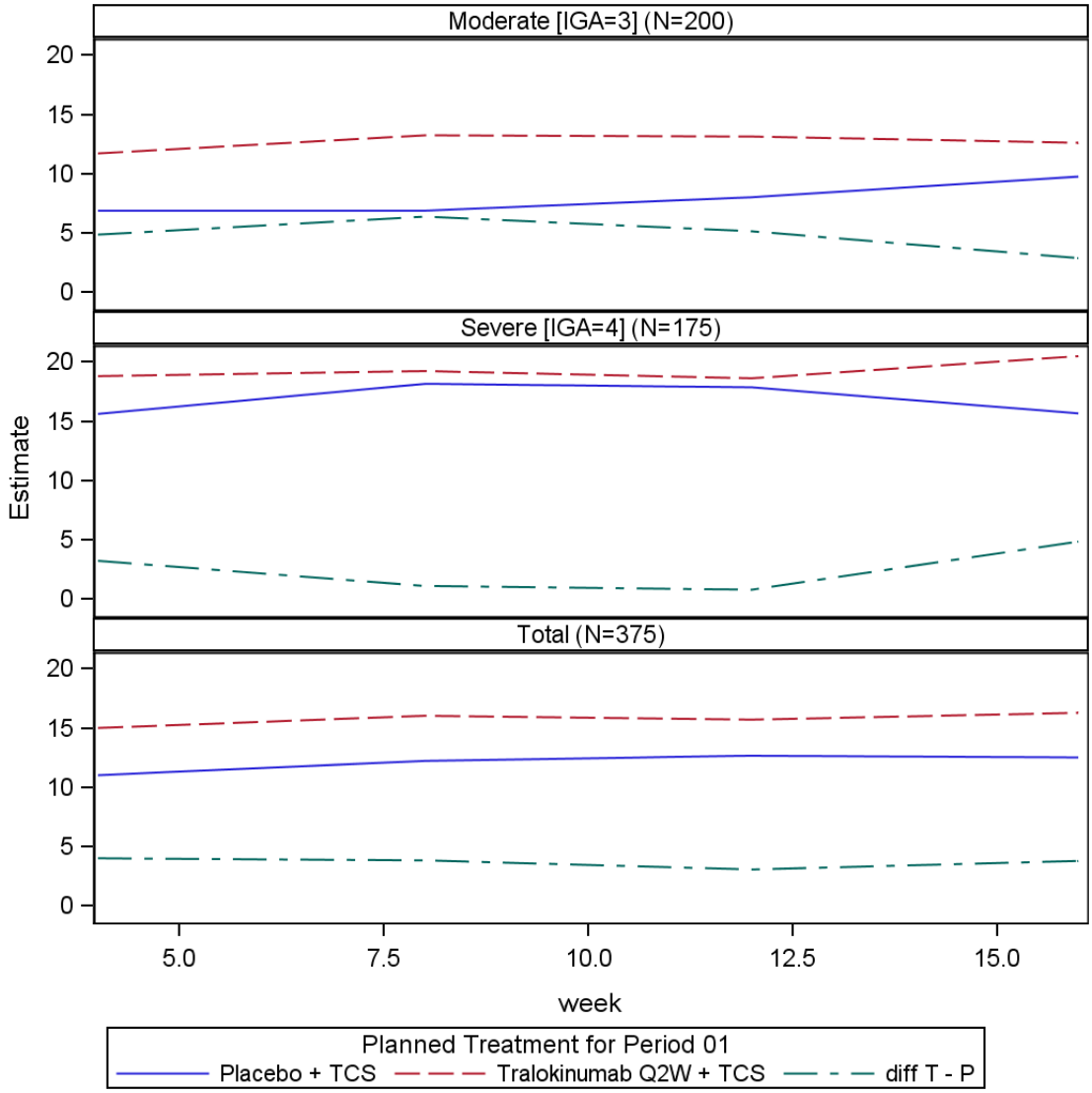
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5754
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid region1 baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*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 1.7.319.3.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]									
Baseline	60	60	52.3 (23.58)		116	115	52.9 (24.51)		
Week 4		58	68.1 (20.30)			114	71.6 (18.67)		
Week 4 chg		58	14.9 (21.11)	15.61 (2.39)		114	18.7 (24.41)	18.81 (1.72)	3.20 (-2.60, 9.00) 0.278 [0.14 (-0.18, 0.45)]
Week 8		57	70.4 (19.17)			110	72.7 (18.86)		
Week 8 chg		57	18.4 (23.70)	18.15 (2.41)		110	19.7 (26.80)	19.23 (1.74)	1.08 (-4.76, 6.92) 0.717 [0.04 (-0.28, 0.36)]
Week 12		53	71.1 (20.74)			104	72.3 (18.02)		
Week 12 chg		53	17.8 (23.19)	17.86 (2.45)		104	19.4 (27.25)	18.62 (1.76)	0.77 (-5.17, 6.70) 0.800 [0.03 (-0.30, 0.36)]
Week 16		56	68.3 (22.88)			108	74.2 (18.45)		
Week 16 chg		56	15.7 (23.25)	15.66 (2.42)		108	21.3 (26.43)	20.49 (1.74)	4.83 (-1.04, 10.70) 0.106 [0.19 (-0.13, 0.51)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5754
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 VAS = Treatment*Week + [Baseline VAS]*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 1.7.319.3.2: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy estimand, LP0162-1339, 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 VAS = Treatment*Week + [Baseline VAS]*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 1.7.325.4.1: Total, Disease severity (IGA), EASI 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	88 (63.8)	15.3 (3.72;26.79)	1.3 (1.06; 1.62)	1.9 (1.16; 3.05)	0.0104	0.0530
Placebo + TCS	137	67 (48.9)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	47 (69.1)	26.7 (11.04;42.40)	1.6 (1.19; 2.22)	3.2 (1.55; 6.47)	0.0014	
Placebo + TCS	70	30 (42.9)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	41 (58.6)	3.7 (-12.8;20.17)	1.1 (0.80; 1.43)	1.2 (0.59; 2.30)	0.6627	
Placebo + TCS	67	37 (55.2)					

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 Prior CSA use and baseline IGA.

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Table 1.7.326.4.1: Total, Disease severity (IGA), EASI 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	57 (41.3)	14.2 (3.21;25.12)	1.5 (1.09; 2.10)	1.9 (1.15; 3.21)	0.0123	0.2071
Placebo + TCS	137	38 (27.7)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	33 (48.5)	21.9 (6.44;37.37)	1.8 (1.16; 2.83)	2.7 (1.30; 5.59)	0.0069	
Placebo + TCS	70	19 (27.1)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	24 (34.3)	6.4 (-8.95;21.69)	1.2 (0.75; 2.01)	1.4 (0.65; 2.82)	0.4197	
Placebo + TCS	67	19 (28.4)					

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 Prior CSA use and baseline IGA.

Table 1.7.329.4.1: Total, Disease severity (IGA), SCORAD 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	40 (29.0)	16.9 (7.55;26.16)	2.4 (1.42; 3.96)	3.0 (1.58; 5.62)	0.0006	0.5673
Placebo + TCS	137	17 (12.4)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	21 (30.9)	19.7 (6.55;32.84)	2.7 (1.31; 5.75)	3.6 (1.45; 9.01)	0.0046	
Placebo + TCS	70	8 (11.4)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	19 (27.1)	14.0 (0.84;27.15)	2.0 (1.00; 4.19)	2.5 (1.02; 5.99)	0.0427	
Placebo + TCS	67	9 (13.4)					

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 Prior CSA use and baseline IGA.

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Table 1.7.330.4.1: Total, Disease severity (IGA), Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	134	62 (46.3)	9.7 (-1.99;21.41)	1.3 (0.95; 1.69)	1.5 (0.92; 2.44)	0.1068	0.9021
Placebo + TCS	135	49 (36.3)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	65	27 (41.5)	8.7 (-7.56;25.05)	1.3 (0.81; 1.97)	1.5 (0.72; 2.93)	0.2958	
Placebo + TCS	70	23 (32.9)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	69	35 (50.7)	10.7 (-6.10;27.47)	1.3 (0.87; 1.85)	1.5 (0.78; 3.05)	0.2177	
Placebo + TCS	65	26 (40.0)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

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Table 1.7.331.4.1: Total, Disease severity (IGA), Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	137	85 (62.0)	11.3 (-0.46;23.02)	1.2 (0.99; 1.51)	1.6 (0.98; 2.55)	0.0614	0.7851
Placebo + TCS	136	69 (50.7)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	67	40 (59.7)	9.9 (-6.79;26.60)	1.2 (0.88; 1.63)	1.5 (0.76; 2.91)	0.2453	
Placebo + TCS	70	35 (50.0)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	45 (64.3)	12.7 (-3.83;29.17)	1.2 (0.93; 1.67)	1.7 (0.85; 3.35)	0.1375	
Placebo + TCS	66	34 (51.5)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 3.

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Table 1.7.333.4.1: Total, Disease severity (IGA), POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	135	105 (77.8)	18.9 (8.08;29.81)	1.3 (1.12; 1.56)	2.5 (1.44; 4.20)	0.0009	0.9021
Placebo + TCS	134	79 (59.0)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	51 (75.0)	19.2 (3.46;34.84)	1.3 (1.04; 1.73)	2.4 (1.14; 4.90)	0.0198	
Placebo + TCS	68	38 (55.9)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	67	54 (80.6)	18.7 (3.71;33.75)	1.3 (1.04; 1.62)	2.6 (1.17; 5.67)	0.0175	
Placebo + TCS	66	41 (62.1)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

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Table 1.7.335.4.1: Total, Disease severity (IGA), DLQI 0/1, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	32 (23.2)	6.9 (-2.56;16.32)	1.4 (0.87; 2.35)	1.5 (0.85; 2.81)	0.1545	0.6380
Placebo + TCS	136	22 (16.2)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	16 (23.5)	8.8 (-4.34;22.03)	1.6 (0.78; 3.36)	1.8 (0.75; 4.21)	0.1884	
Placebo + TCS	69	10 (14.5)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	16 (22.9)	4.9 (-8.60;18.43)	1.3 (0.65; 2.52)	1.4 (0.59; 3.12)	0.4790	
Placebo + TCS	67	12 (17.9)					

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 Prior CSA use and baseline IGA.

Table 1.7.355.4.1: Total, Disease severity (IGA), EASI 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	96 (69.6)	16.8 (5.65;27.89)	1.3 (1.09; 1.59)	2.1 (1.27; 3.49)	0.0039	0.8830
Placebo + TCS	137	73 (53.3)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	51 (75.0)	16.9 (1.92;31.98)	1.3 (1.02; 1.63)	2.3 (1.07; 4.81)	0.0312	
Placebo + TCS	70	41 (58.6)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	45 (64.3)	16.6 (0.20;33.00)	1.3 (0.99; 1.83)	2.0 (1.00; 3.92)	0.0521	
Placebo + TCS	67	32 (47.8)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.7.356.4.1: Total, Disease severity (IGA), EASI 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	67 (48.6)	14.1 (2.87;25.40)	1.4 (1.06; 1.86)	1.8 (1.12; 3.04)	0.0160	0.6403
Placebo + TCS	137	48 (35.0)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	36 (52.9)	12.1 (-4.01;28.13)	1.3 (0.91; 1.83)	1.7 (0.84; 3.35)	0.1477	
Placebo + TCS	70	29 (41.4)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	31 (44.3)	16.2 (0.44;31.99)	1.6 (0.99; 2.50)	2.1 (1.00; 4.20)	0.0495	
Placebo + TCS	67	19 (28.4)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.7.359.4.1: Total, Disease severity (IGA), SCORAD 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	53 (38.4)	20.6 (10.39;30.82)	2.1 (1.42; 3.22)	3.0 (1.68; 5.21)	0.0001	0.2140
Placebo + TCS	137	25 (18.2)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	29 (42.6)	27.4 (13.32;41.49)	2.8 (1.52; 5.03)	4.5 (1.93;10.45)	0.0003	
Placebo + TCS	70	11 (15.7)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	24 (34.3)	13.7 (-0.89;28.39)	1.7 (0.94; 2.94)	2.0 (0.93; 4.44)	0.0722	
Placebo + TCS	67	14 (20.9)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.7.360.4.1: Total, Disease severity (IGA), Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	134	64 (47.8)	8.3 (-3.43;20.09)	1.2 (0.92; 1.60)	1.4 (0.87; 2.29)	0.1650	0.0628
Placebo + TCS	135	53 (39.3)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	65	26 (40.0)	-2.7 (-19.2;13.80)	0.9 (0.63; 1.40)	0.9 (0.45; 1.78)	0.7495	
Placebo + TCS	70	30 (42.9)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	69	38 (55.1)	19.4 (3.08;35.77)	1.5 (1.05; 2.28)	2.3 (1.12; 4.56)	0.0231	
Placebo + TCS	65	23 (35.4)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.7.361.4.1: Total, Disease severity (IGA), Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	137	86 (62.8)	16.0 (4.45;27.60)	1.3 (1.08; 1.67)	1.9 (1.19; 3.16)	0.0078	0.6205
Placebo + TCS	136	64 (47.1)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	67	43 (64.2)	13.1 (-3.12;29.26)	1.3 (0.94; 1.67)	1.7 (0.87; 3.48)	0.1191	
Placebo + TCS	70	36 (51.4)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	43 (61.4)	19.0 (2.49;35.51)	1.4 (1.03; 2.03)	2.2 (1.09; 4.29)	0.0278	
Placebo + TCS	66	28 (42.4)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.7.363.4.1: Total, Disease severity (IGA), POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	135	105 (77.8)	21.3 (10.39;32.18)	1.4 (1.16; 1.64)	2.7 (1.59; 4.63)	0.0002	0.8456
Placebo + TCS	134	76 (56.7)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	54 (79.4)	19.4 (4.37;34.43)	1.3 (1.05; 1.66)	2.6 (1.20; 5.58)	0.0141	
Placebo + TCS	68	41 (60.3)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	67	51 (76.1)	23.2 (7.43;38.99)	1.4 (1.10; 1.87)	2.8 (1.35; 5.97)	0.0055	
Placebo + TCS	66	35 (53.0)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.7.365.4.1: Total, Disease severity (IGA), DLQI 0/1, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	36 (26.1)	13.7 (4.62;22.81)	2.1 (1.25; 3.56)	2.5 (1.34; 4.85)	0.0038	0.8233
Placebo + TCS	136	17 (12.5)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	23 (33.8)	18.0 (3.88;32.20)	2.1 (1.13; 4.07)	2.7 (1.20; 6.19)	0.0151	
Placebo + TCS	69	11 (15.9)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	13 (18.6)	9.4 (-1.95;20.72)	2.0 (0.83; 5.06)	2.3 (0.81; 6.47)	0.1119	
Placebo + TCS	67	6 (9.0)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.7.385.4.1: Total, Disease severity (IGA), SCORAD 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	13 (9.4)	4.5 (-1.61;10.59)	1.9 (0.78; 4.54)	2.0 (0.77; 5.17)	0.1522	0.5712
Placebo + TCS	137	7 (5.1)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	7 (10.3)	6.2 (-2.37;14.73)	2.5 (0.67; 9.12)	2.7 (0.65;11.23)	0.1609	
Placebo + TCS	70	3 (4.3)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	6 (8.6)	2.8 (-5.93;11.49)	1.5 (0.44; 4.90)	1.5 (0.41; 5.58)	0.5328	
Placebo + TCS	67	4 (6.0)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

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Table 1.7.389.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)							
Total							
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)		
Week 16		123 4.2 (2.30)			124 3.3 (2.05)		
Week 16 chg		122 -3.3 (2.36)	-3.21 (0.19)		123 -3.9 (2.06)	-3.98 (0.19)	-0.77 (-1.30, -0.24) 0.004 [-0.35 (-0.60, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4201
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.389.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 7.4 (1.36)		68	67 6.9 (1.39)			
Week 16		62 4.4 (2.27)			59 3.2 (2.13)			
Week 16 chg		62 -3.0 (2.40)	-2.88 (0.27)		58 -3.8 (2.03)	-3.87 (0.28)	-0.99 (-1.77, -0.22) [-0.45 (-0.81, -0.08)]	0.013

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4201
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.389.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 7.6 (1.38)		70	70 7.6 (1.45)			
Week 16		61 4.1 (2.34)			65 3.5 (1.97)			
Week 16 chg		60 -3.6 (2.30)	-3.53 (0.27)		65 -4.1 (2.09)	-4.10 (0.26)	-0.56 (-1.30, 0.17) [-0.26 (-0.61, 0.10)]	0.132

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4201
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.390.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 16		123 3.2 (2.41)			124 2.4 (2.16)		
Week 16 chg		122 -3.7 (2.29)	-3.50 (0.19)		123 -3.9 (2.32)	-4.03 (0.19)	-0.53 (-1.07, 0.01) 0.052 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3011
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.390.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 6.7 (1.60)		68	67 6.0 (2.00)			
Week 16		62 3.3 (2.30)			59 2.2 (2.06)			
Week 16 chg		62 -3.4 (2.19)	-3.25 (0.26)		58 -3.9 (2.16)	-4.05 (0.26)	-0.80 (-1.53, -0.06) [-0.37 (-0.73, -0.00)]	0.034

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3011
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.390.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 7.1 (1.68)		70	70 6.6 (2.18)		
Week 16		61 3.2 (2.53)			65 2.7 (2.24)		
Week 16 chg		60 -3.9 (2.39)	-3.76 (0.29)		65 -3.9 (2.46)	-4.03 (0.27)	-0.27 (-1.05, 0.52) 0.506 [-0.11 (-0.46, 0.24)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3011
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.391.4.1: Total, Disease severity (IGA), change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
SCORAD Score								
Total								
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)			
Week 16		124 36.3 (18.78)			123 27.0 (16.90)			
Week 16 chg		124 -34.7 (19.94)	-34.36 (1.54)		123 -43.3 (19.46)	-43.61 (1.55)	-9.25 (-13.6, -4.94) [-0.47 (-0.72, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3122
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.391.4.1: Total, Disease severity (IGA), change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 64.0 (9.94)		68	68 64.0 (8.43)			
Week 16		61 34.7 (16.62)			59 23.1 (14.43)			
Week 16 chg		61 -29.5 (19.49)	-29.19 (1.91)		59 -40.5 (15.58)	-40.80 (1.94)	-11.61 (-17.0, -6.21) [-0.66 (-1.02, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3122
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.391.4.1: Total, Disease severity (IGA), change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	67 77.9 (11.69)		70	70 76.2 (12.00)			
Week 16		63 37.9 (20.66)			64 30.5 (18.29)			
Week 16 chg		63 -39.8 (19.17)	-39.25 (2.40)		64 -45.8 (22.27)	-46.23 (2.38)	-6.98 (-13.7, -0.28) [-0.34 (-0.69, 0.01)]	0.041

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3122
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.392.4.1: Total, Disease severity (IGA), change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 16		122 6.4 (5.60)			119 4.5 (3.87)		
Week 16 chg		120 -10.0 (6.54)	-9.61 (0.40)		118 -11.0 (5.99)	-11.29 (0.41)	-1.68 (-2.82, -0.55) 0.004 [-0.27 (-0.52, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1319
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.392.4.1: Total, Disease severity (IGA), change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	68 15.0 (6.67)		68	68 15.2 (5.87)			
Week 16		60 6.6 (5.82)			56 4.0 (3.93)			
Week 16 chg		59 -8.2 (6.22)	-8.17 (0.56)		56 -10.6 (5.40)	-10.72 (0.58)	-2.56 (-4.16, -0.95) [-0.44 (-0.81, -0.07)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1319
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.392.4.1: Total, Disease severity (IGA), change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 17.8 (5.68)		70	69 16.5 (7.10)			
Week 16		62 6.3 (5.42)			63 4.8 (3.79)			
Week 16 chg		61 -11.6 (6.46)	-10.96 (0.57)		62 -11.3 (6.52)	-11.92 (0.57)	-0.96 (-2.56, 0.65) [-0.15 (-0.50, 0.21)]	0.240

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1319
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.393.4.1: Total, Disease severity (IGA), change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total												
Total												
Baseline	137	134	20.9 (5.72)			138	135	21.3 (5.12)				
Week 16		122	12.9 (7.67)				119	9.0 (5.53)				
Week 16 chg		120	-8.0 (8.09)	-8.10	(0.59)		116	-12.2 (6.39)	-12.12	(0.60)	-4.02 (-5.68, -2.36) [-0.55 (-0.81, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6651
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.393.4.1: Total, Disease severity (IGA), change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	68 20.0 (6.11)		68	68 21.3 (4.52)			
Week 16		60 12.6 (7.55)			56 8.8 (6.03)			
Week 16 chg		59 -7.3 (7.60)	-7.70 (0.85)		56 -12.5 (6.90)	-12.12 (0.88)	-4.42 (-6.85, -1.99) [-0.61 (-0.98, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6651
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.393.4.1: Total, Disease severity (IGA), change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 21.8 (5.18)		70	67 21.3 (5.71)			
Week 16		62 13.2 (7.83)			63 9.2 (5.09)			
Week 16 chg		61 -8.7 (8.56)	-8.47 (0.83)		60 -11.9 (5.92)	-12.14 (0.84)	-3.67 (-6.00, -1.34) [-0.50 (-0.86, -0.14)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6651
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.395.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 16		122	69.3 (21.69)			119	75.7 (16.92)		
Week 16 chg		120	16.7 (26.74)	14.64 (1.75)		116	17.7 (22.49)	19.84 (1.78)	5.21 (0.28, 10.14) 0.039 [0.21 (-0.05, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1214
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.395.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]												
Baseline	70	68	55.4 (21.46)			68	68	58.6 (17.74)				
Week 16		60	68.7 (23.55)				56	78.6 (16.72)				
Week 16 chg		59	12.3 (25.61)	10.75	(2.56)		56	18.1 (21.44)	19.51	(2.63)	8.76 (1.46, 16.06) [0.37 (0.00, 0.74)]	0.019

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1214
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.395.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 49.5 (22.25)		70	67 54.6 (21.83)		
Week 16		62 69.9 (19.91)			63 73.2 (16.83)		
Week 16 chg		61 21.0 (27.32)	18.25 (2.36)		60 17.4 (23.60)	20.13 (2.38)	1.87 (-4.81, 8.55) 0.580 [0.07 (-0.28, 0.43)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1214
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.396.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss								
Total								
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)			
Week 16		124 2.7 (2.77)			123 1.9 (2.39)			
Week 16 chg		124 -4.1 (3.25)	-3.99 (0.23)		123 -4.7 (2.92)	-4.72 (0.23)	-0.73 (-1.36, -0.09) [-0.23 (-0.48, 0.02)]	0.025

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1858
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.396.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 6.4 (2.27)		68	68 6.5 (2.15)			
Week 16		61 2.8 (2.63)			59 1.7 (2.29)			
Week 16 chg		61 -3.5 (3.20)	-3.59 (0.31)		59 -4.8 (2.55)	-4.75 (0.31)	-1.17 (-2.04, -0.30) [-0.40 (-0.76, -0.04)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1858
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.396.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	67 7.1 (2.09)		70	70 6.8 (2.56)			
Week 16		63 2.6 (2.91)			64 2.2 (2.48)			
Week 16 chg		63 -4.6 (3.25)	-4.38 (0.34)		64 -4.5 (3.25)	-4.69 (0.33)	-0.32 (-1.25, 0.62) [-0.10 (-0.45, 0.25)]	0.506

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1858
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.398.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 26		115	72.6 (20.73)			119	76.4 (17.30)		
Week 26 chg		113	20.5 (25.83)	18.74 (1.72)		116	19.5 (21.18)	21.31 (1.70)	2.56 (-2.22, 7.35) 0.292 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0908
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.398.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]												
Baseline	70	68	55.4 (21.46)			68	68	58.6 (17.74)				
Week 26		56	71.9 (22.56)				56	79.3 (16.21)				
Week 26 chg		55	16.6 (26.28)	15.33	(2.56)		56	21.0 (20.75)	22.21	(2.53)	6.87 (-0.28, 14.03) [0.29 (-0.08, 0.66)]	0.059

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0908
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.398.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 49.5 (22.25)		70	67 54.6 (21.83)		
Week 26		59 73.3 (18.99)			63 73.8 (17.94)		
Week 26 chg		58 24.2 (25.06)	21.83 (2.30)		60 18.1 (21.65)	20.41 (2.26)	-1.41 (-7.85, 5.02) 0.664 [-0.06 (-0.42, 0.30)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0908
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.401.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.56 (0.82)		138 -12.9 (10.72)	-13.28 (0.82)	-0.72 (-3.02, 1.57) 0.536 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.48 (0.83)		137 -18.8 (10.58)	-19.37 (0.82)	-1.88 (-4.18, 0.42) 0.109 [-0.17 (-0.41, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.42 (0.83)		134 -20.9 (11.93)	-21.43 (0.83)	-3.01 (-5.32, -0.70) 0.011 [-0.25 (-0.49, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.19 (0.83)		130 -22.5 (12.16)	-23.11 (0.83)	-3.92 (-6.23, -1.60) <.001 [-0.30 (-0.54, -0.06)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.50 (0.83)		130 -24.3 (11.55)	-24.96 (0.83)	-4.46 (-6.78, -2.14) <.001 [-0.35 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-20.99 (0.84)		128 -24.7 (12.40)	-25.11 (0.84)	-4.13 (-6.46, -1.80) <.001 [-0.31 (-0.56, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7211
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.401.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 11.2 (11.57)			127 7.0 (8.34)		
Week 14 chg		126 -22.8 (14.69)	-21.74 (0.84)		127 -25.1 (13.29)	-25.62 (0.84)	-3.87 (-6.21, -1.54) 0.001 [-0.28 (-0.52, -0.03)]
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.54 (0.84)		123 -25.9 (12.78)	-26.06 (0.84)	-3.52 (-5.86, -1.17) 0.003 [-0.25 (-0.50, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7211
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.401.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 27.1 (7.27)		68	68 26.0 (5.96)		
Week 2		70 16.0 (9.13)			68 13.0 (8.66)		
Week 2 chg		70 -11.1 (10.82)	-10.76 (0.97)		68 -13.1 (8.06)	-13.44 (0.98)	-2.68 (-5.40, 0.04) 0.054 [-0.28 (-0.62, 0.06)]
Week 4		69 11.7 (8.80)			68 8.7 (7.42)		
Week 4 chg		69 -15.5 (11.32)	-14.98 (0.97)		68 -17.3 (7.88)	-17.77 (0.98)	-2.79 (-5.52, -0.06) 0.045 [-0.29 (-0.62, 0.05)]
Week 6		67 11.3 (9.02)			66 8.1 (7.87)		
Week 6 chg		67 -15.9 (10.08)	-15.59 (0.98)		66 -18.1 (8.01)	-18.37 (0.99)	-2.78 (-5.52, -0.03) 0.048 [-0.30 (-0.65, 0.04)]
Week 8		67 11.4 (10.71)			62 6.7 (6.06)		
Week 8 chg		67 -15.7 (12.14)	-15.42 (0.98)		62 -19.1 (6.75)	-19.51 (1.01)	-4.10 (-6.87, -1.33) 0.004 [-0.41 (-0.76, -0.06)]
Week 10		66 10.7 (10.29)			63 5.0 (5.22)		
Week 10 chg		66 -16.3 (12.52)	-15.92 (0.98)		63 -20.9 (6.55)	-21.21 (1.00)	-5.29 (-8.06, -2.52) <.001 [-0.53 (-0.88, -0.17)]
Week 12		65 9.9 (9.55)			61 4.6 (5.04)		
Week 12 chg		65 -17.3 (11.97)	-16.65 (0.99)		61 -21.4 (6.93)	-21.68 (1.01)	-5.02 (-7.81, -2.24) <.001 [-0.51 (-0.86, -0.15)]
Week 14		63 9.8 (9.49)			62 4.7 (5.54)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7211
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.401.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	63	-17.2 (11.53)	-16.94 (0.99)	62	-21.2 (7.38)	-21.57 (1.01)	-4.63 (-7.42, -1.84) 0.001 [-0.48 (-0.83, -0.12)]
Week 16	61	9.0 (9.13)		59	4.3 (5.71)		
Week 16 chg	61	-18.1 (12.07)	-17.35 (1.00)	59	-21.8 (7.75)	-21.89 (1.02)	-4.54 (-7.35, -1.72) 0.002 [-0.45 (-0.81, -0.08)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7211
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.401.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	67 40.9 (14.81)		70	70 38.0 (12.58)		
Week 2		67 26.1 (16.11)			70 25.3 (13.21)		
Week 2 chg		67 -14.8 (11.29)	-14.24 (1.34)		70 -12.7 (12.84)	-13.20 (1.32)	1.04 (-2.67, 4.76) 0.580 [0.09 (-0.25, 0.42)]
Week 4		65 19.9 (14.55)			69 17.4 (11.10)		
Week 4 chg		65 -21.1 (11.96)	-19.83 (1.35)		69 -20.3 (12.58)	-20.98 (1.32)	-1.15 (-4.89, 2.59) 0.545 [-0.09 (-0.43, 0.25)]
Week 6		65 18.3 (14.34)			68 14.2 (10.36)		
Week 6 chg		65 -22.7 (14.05)	-21.17 (1.35)		68 -23.6 (14.31)	-24.45 (1.32)	-3.28 (-7.03, 0.46) 0.085 [-0.23 (-0.57, 0.11)]
Week 8		66 16.7 (14.06)			68 12.2 (9.54)		
Week 8 chg		66 -24.2 (14.25)	-22.90 (1.35)		68 -25.6 (14.93)	-26.54 (1.32)	-3.64 (-7.37, 0.10) 0.056 [-0.25 (-0.59, 0.09)]
Week 10		65 14.3 (12.74)			67 10.1 (8.33)		
Week 10 chg		65 -26.7 (13.45)	-25.01 (1.35)		67 -27.4 (14.11)	-28.57 (1.33)	-3.57 (-7.31, 0.18) 0.062 [-0.26 (-0.60, 0.08)]
Week 12		63 14.2 (12.40)			67 10.4 (8.91)		
Week 12 chg		63 -27.2 (14.75)	-25.16 (1.36)		67 -27.7 (15.26)	-28.52 (1.33)	-3.36 (-7.12, 0.40) 0.079 [-0.22 (-0.57, 0.12)]
Week 14		63 12.7 (13.24)			65 9.2 (9.89)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7211
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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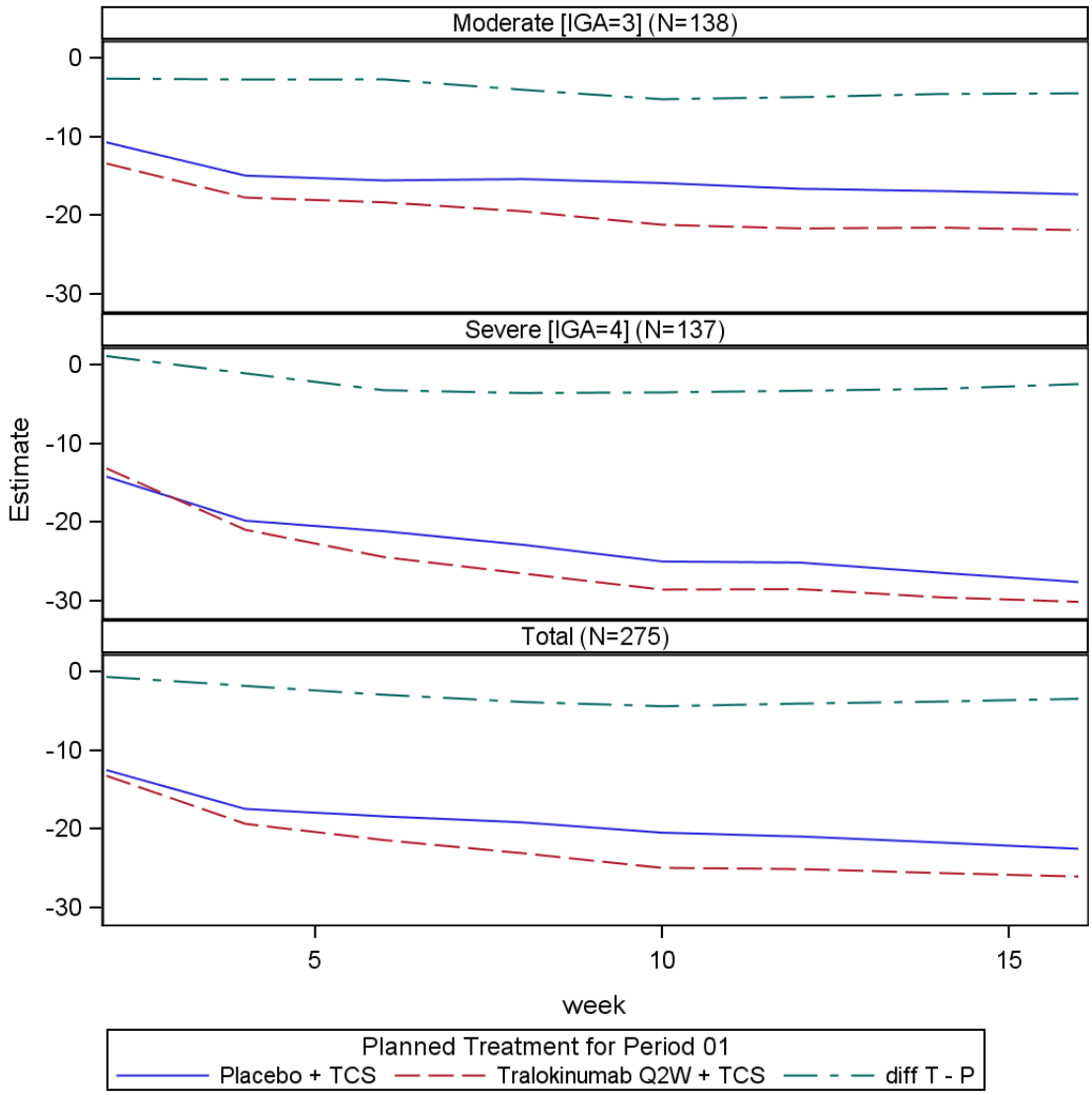
Table 1.7.401.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	63	-28.3 (15.47)	-26.44 (1.36)	65	-28.9 (16.34)	-29.55 (1.33)	-3.12 (-6.88, 0.65) [-0.20 (-0.54, 0.15)]	0.105
Week 16	63	12.0 (13.18)		64	8.4 (8.64)			
Week 16 chg	63	-29.2 (15.48)	-27.62 (1.36)	64	-29.6 (15.20)	-30.12 (1.34)	-2.51 (-6.28, 1.27) [-0.16 (-0.51, 0.19)]	0.192

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7211
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.401.4.2: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.7.403.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)								
Total								
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)			
Week 1		135 6.3 (1.69)			136 6.0 (1.78)			
Week 1 chg		135 -1.1 (1.34)	-1.14 (0.17)		136 -1.2 (1.31)	-1.23 (0.17)	-0.08 (-0.56, 0.39) [-0.06 (-0.30, 0.18)]	0.732
Week 2		134 5.8 (1.97)			132 5.4 (2.11)			
Week 2 chg		134 -1.7 (1.78)	-1.67 (0.17)		132 -1.9 (1.67)	-1.92 (0.17)	-0.24 (-0.72, 0.24) [-0.14 (-0.38, 0.10)]	0.324
Week 3		133 5.3 (2.17)			131 4.8 (2.08)			
Week 3 chg		133 -2.2 (2.12)	-2.11 (0.17)		131 -2.5 (1.84)	-2.53 (0.17)	-0.42 (-0.90, 0.06) [-0.21 (-0.45, 0.03)]	0.088
Week 4		130 5.1 (2.25)			133 4.4 (2.14)			
Week 4 chg		130 -2.4 (2.14)	-2.29 (0.17)		133 -2.8 (1.92)	-2.87 (0.17)	-0.58 (-1.06, -0.10) [-0.28 (-0.53, -0.04)]	0.019
Week 5		131 4.9 (2.37)			129 4.2 (2.15)			
Week 5 chg		131 -2.6 (2.26)	-2.54 (0.17)		129 -3.1 (1.92)	-3.16 (0.17)	-0.62 (-1.10, -0.14) [-0.30 (-0.54, -0.05)]	0.012
Week 6		130 4.8 (2.35)			129 4.2 (2.16)			
Week 6 chg		130 -2.7 (2.25)	-2.58 (0.17)		129 -3.1 (1.99)	-3.14 (0.17)	-0.57 (-1.05, -0.08) [-0.27 (-0.51, -0.02)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8585
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.403.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7		129 4.7 (2.24)			128 4.0 (2.13)			
Week 7 chg		129 -2.8 (2.25)	-2.73 (0.17)		128 -3.3 (2.05)	-3.38 (0.17)	-0.65 (-1.13, -0.16) [-0.30 (-0.55, -0.05)]	0.009
Week 8		127 4.7 (2.32)			125 3.7 (2.10)			
Week 8 chg		127 -2.8 (2.27)	-2.73 (0.17)		125 -3.7 (1.96)	-3.64 (0.17)	-0.92 (-1.40, -0.43) [-0.43 (-0.68, -0.18)]	<.001
Week 9		127 4.6 (2.37)			127 3.6 (2.10)			
Week 9 chg		127 -2.9 (2.32)	-2.79 (0.17)		127 -3.7 (2.03)	-3.71 (0.17)	-0.92 (-1.40, -0.44) [-0.42 (-0.67, -0.17)]	<.001
Week 10		125 4.5 (2.42)			122 3.6 (2.11)			
Week 10 chg		125 -2.9 (2.39)	-2.87 (0.17)		122 -3.7 (1.93)	-3.70 (0.17)	-0.83 (-1.32, -0.35) [-0.38 (-0.63, -0.13)]	<.001
Week 11		128 4.4 (2.41)			126 3.5 (2.15)			
Week 11 chg		128 -3.1 (2.40)	-3.06 (0.17)		126 -3.7 (1.97)	-3.75 (0.17)	-0.70 (-1.18, -0.21) [-0.32 (-0.56, -0.07)]	0.005
Week 12		123 4.4 (2.36)			121 3.5 (2.08)			
Week 12 chg		123 -3.1 (2.41)	-3.03 (0.17)		121 -3.8 (2.06)	-3.82 (0.17)	-0.80 (-1.28, -0.31) [-0.35 (-0.61, -0.10)]	0.001
Week 13		116 4.3 (2.38)			120 3.3 (2.06)			
Week 13 chg		116 -3.3 (2.35)	-3.09 (0.18)		120 -4.0 (2.09)	-3.92 (0.17)	-0.84 (-1.32, -0.35) [-0.38 (-0.63, -0.12)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8585
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.403.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.13 (0.17)	123	-3.9 (2.12)	-3.85 (0.17)	-0.72 (-1.20, -0.23) [-0.32 (-0.57, -0.07)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.16 (0.17)	123	-4.0 (2.15)	-3.93 (0.17)	-0.76 (-1.25, -0.28) [-0.34 (-0.59, -0.09)]	0.002
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.10 (0.17)	122	-3.9 (2.06)	-3.93 (0.17)	-0.83 (-1.32, -0.35) [-0.38 (-0.63, -0.12)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8585
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.403.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 7.4 (1.36)		68	67 6.9 (1.39)		
Week 1		69 6.5 (1.60)			66 5.7 (1.76)		
Week 1 chg		69 -0.9 (1.26)	-0.86 (0.24)		66 -1.2 (1.42)	-1.22 (0.25)	-0.36 (-1.04, 0.32) 0.303 [-0.26 (-0.60, 0.07)]
Week 2		69 6.1 (1.98)			66 5.1 (2.10)		
Week 2 chg		69 -1.3 (1.81)	-1.23 (0.24)		66 -1.8 (1.69)	-1.91 (0.25)	-0.68 (-1.36, 0.00) 0.051 [-0.39 (-0.73, -0.05)]
Week 3		68 5.6 (2.20)			64 4.6 (2.00)		
Week 3 chg		68 -1.8 (2.14)	-1.63 (0.24)		64 -2.3 (1.80)	-2.40 (0.25)	-0.77 (-1.45, -0.09) 0.027 [-0.39 (-0.73, -0.04)]
Week 4		68 5.4 (2.31)			65 4.3 (2.16)		
Week 4 chg		68 -2.0 (2.20)	-1.88 (0.24)		65 -2.6 (1.92)	-2.71 (0.25)	-0.83 (-1.51, -0.15) 0.017 [-0.40 (-0.75, -0.06)]
Week 5		68 5.1 (2.34)			65 4.1 (2.21)		
Week 5 chg		68 -2.3 (2.25)	-2.17 (0.24)		65 -2.9 (1.89)	-2.94 (0.25)	-0.78 (-1.46, -0.10) 0.025 [-0.37 (-0.72, -0.03)]
Week 6		66 5.0 (2.25)			63 4.2 (2.30)		
Week 6 chg		66 -2.4 (2.08)	-2.28 (0.24)		63 -2.7 (1.95)	-2.79 (0.25)	-0.51 (-1.19, 0.17) 0.144 [-0.25 (-0.60, 0.09)]
Week 7		66 4.9 (2.14)			62 3.9 (2.17)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8585
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.403.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	66	-2.5 (2.07)	-2.36 (0.24)	62	-3.1 (2.01)	-3.11 (0.25)	-0.76 (-1.44, -0.07) [-0.37 (-0.72, -0.02)]	0.031
Week 8		65 4.8 (2.14)			60 3.5 (2.18)			
Week 8 chg	65	-2.5 (2.04)	-2.41 (0.24)	60	-3.4 (1.98)	-3.46 (0.25)	-1.05 (-1.73, -0.36) [-0.52 (-0.88, -0.16)]	0.003
Week 9		64 4.9 (2.18)			60 3.5 (2.09)			
Week 9 chg	64	-2.5 (2.14)	-2.43 (0.24)	60	-3.6 (1.98)	-3.57 (0.25)	-1.15 (-1.84, -0.46) [-0.56 (-0.92, -0.20)]	0.001
Week 10		65 4.7 (2.38)			59 3.6 (2.21)			
Week 10 chg	65	-2.6 (2.33)	-2.53 (0.24)	59	-3.4 (2.00)	-3.44 (0.25)	-0.90 (-1.59, -0.22) [-0.41 (-0.77, -0.06)]	0.010
Week 11		64 4.6 (2.37)			60 3.4 (2.12)			
Week 11 chg	64	-2.7 (2.35)	-2.65 (0.24)	60	-3.5 (1.91)	-3.59 (0.25)	-0.94 (-1.63, -0.25) [-0.44 (-0.79, -0.08)]	0.008
Week 12		63 4.7 (2.43)			60 3.2 (1.95)			
Week 12 chg	63	-2.7 (2.46)	-2.57 (0.24)	60	-3.7 (1.88)	-3.78 (0.25)	-1.21 (-1.90, -0.52) [-0.55 (-0.91, -0.19)]	<.001
Week 13		58 4.6 (2.47)			57 3.1 (2.05)			
Week 13 chg	58	-2.9 (2.38)	-2.68 (0.25)	57	-3.7 (2.05)	-3.76 (0.25)	-1.09 (-1.78, -0.39) [-0.49 (-0.86, -0.12)]	0.002
Week 14		64 4.4 (2.47)			59 3.2 (2.17)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8585
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.403.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	64	-3.0 (2.33)	-2.81 (0.24)	59	-3.7 (2.08)	-3.71 (0.25)	-0.90 (-1.59, -0.22) [-0.41 (-0.77, -0.05)]	0.010
Week 15	63	4.5 (2.32)		59	3.2 (2.18)			
Week 15 chg	63	-3.0 (2.28)	-2.71 (0.24)	59	-3.8 (2.15)	-3.81 (0.25)	-1.10 (-1.78, -0.41) [-0.49 (-0.85, -0.13)]	0.002
Week 16	61	4.3 (2.26)		57	3.2 (2.15)			
Week 16 chg	61	-3.0 (2.38)	-2.73 (0.24)	57	-3.7 (2.04)	-3.78 (0.25)	-1.05 (-1.74, -0.36) [-0.47 (-0.84, -0.11)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8585
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 14:20 LP0162-Payer /p_mmrm3/t_t_igag_g03_46_w16.txt

Table 1.7.403.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 7.6 (1.38)		70	70 7.6 (1.45)			
Week 1		66 6.2 (1.79)			70 6.3 (1.77)			
Week 1 chg		66 -1.4 (1.37)	-1.42 (0.25)		70 -1.3 (1.20)	-1.26 (0.24)	0.16 (-0.53, 0.84) [0.12 (-0.22, 0.46)]	0.654
Week 2		65 5.5 (1.93)			66 5.7 (2.08)			
Week 2 chg		65 -2.1 (1.64)	-2.13 (0.25)		66 -1.9 (1.66)	-1.94 (0.24)	0.19 (-0.50, 0.88) [0.11 (-0.23, 0.46)]	0.595
Week 3		65 5.0 (2.10)			67 4.9 (2.16)			
Week 3 chg		65 -2.6 (2.02)	-2.60 (0.25)		67 -2.7 (1.86)	-2.68 (0.24)	-0.08 (-0.77, 0.61) [-0.04 (-0.38, 0.30)]	0.827
Week 4		62 4.8 (2.16)			68 4.6 (2.13)			
Week 4 chg		62 -2.8 (2.00)	-2.71 (0.25)		68 -3.0 (1.91)	-3.02 (0.24)	-0.31 (-1.00, 0.38) [-0.16 (-0.50, 0.19)]	0.377
Week 5		63 4.6 (2.40)			64 4.3 (2.09)			
Week 5 chg		63 -3.0 (2.22)	-2.93 (0.25)		64 -3.3 (1.95)	-3.37 (0.25)	-0.44 (-1.13, 0.25) [-0.21 (-0.56, 0.14)]	0.210
Week 6		64 4.7 (2.45)			66 4.2 (2.03)			
Week 6 chg		64 -3.0 (2.39)	-2.91 (0.25)		66 -3.5 (1.97)	-3.47 (0.24)	-0.56 (-1.25, 0.13) [-0.26 (-0.60, 0.09)]	0.111
Week 7		63 4.4 (2.34)			66 4.0 (2.10)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8585
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.403.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	63	-3.2 (2.38)	-3.12 (0.25)	66	-3.6 (2.06)	-3.62 (0.24)	-0.50 (-1.19, 0.19) [-0.22 (-0.57, 0.12)]	0.157
Week 8	62	4.5 (2.50)		65	3.8 (2.04)			
Week 8 chg	62	-3.1 (2.46)	-3.06 (0.25)	65	-3.9 (1.93)	-3.83 (0.24)	-0.76 (-1.46, -0.07) [-0.35 (-0.70, 0.00)]	0.030
Week 9	63	4.4 (2.55)		67	3.8 (2.12)			
Week 9 chg	63	-3.3 (2.45)	-3.16 (0.25)	67	-3.8 (2.07)	-3.85 (0.24)	-0.69 (-1.38, 0.00) [-0.30 (-0.65, 0.04)]	0.051
Week 10	60	4.3 (2.45)		63	3.7 (2.03)			
Week 10 chg	60	-3.3 (2.41)	-3.22 (0.25)	63	-4.0 (1.85)	-3.97 (0.25)	-0.74 (-1.44, -0.05) [-0.35 (-0.70, 0.01)]	0.036
Week 11	64	4.1 (2.44)		66	3.7 (2.18)			
Week 11 chg	64	-3.5 (2.39)	-3.48 (0.25)	66	-3.9 (2.02)	-3.93 (0.24)	-0.45 (-1.14, 0.24) [-0.20 (-0.55, 0.14)]	0.200
Week 12	60	4.0 (2.27)		61	3.8 (2.18)			
Week 12 chg	60	-3.6 (2.27)	-3.50 (0.25)	61	-3.8 (2.24)	-3.88 (0.25)	-0.38 (-1.08, 0.31) [-0.17 (-0.53, 0.19)]	0.280
Week 13	58	4.1 (2.27)		63	3.5 (2.07)			
Week 13 chg	58	-3.6 (2.28)	-3.51 (0.25)	63	-4.2 (2.12)	-4.08 (0.25)	-0.57 (-1.26, 0.13) [-0.26 (-0.62, 0.10)]	0.109
Week 14	59	4.1 (2.30)		64	3.6 (2.10)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8585
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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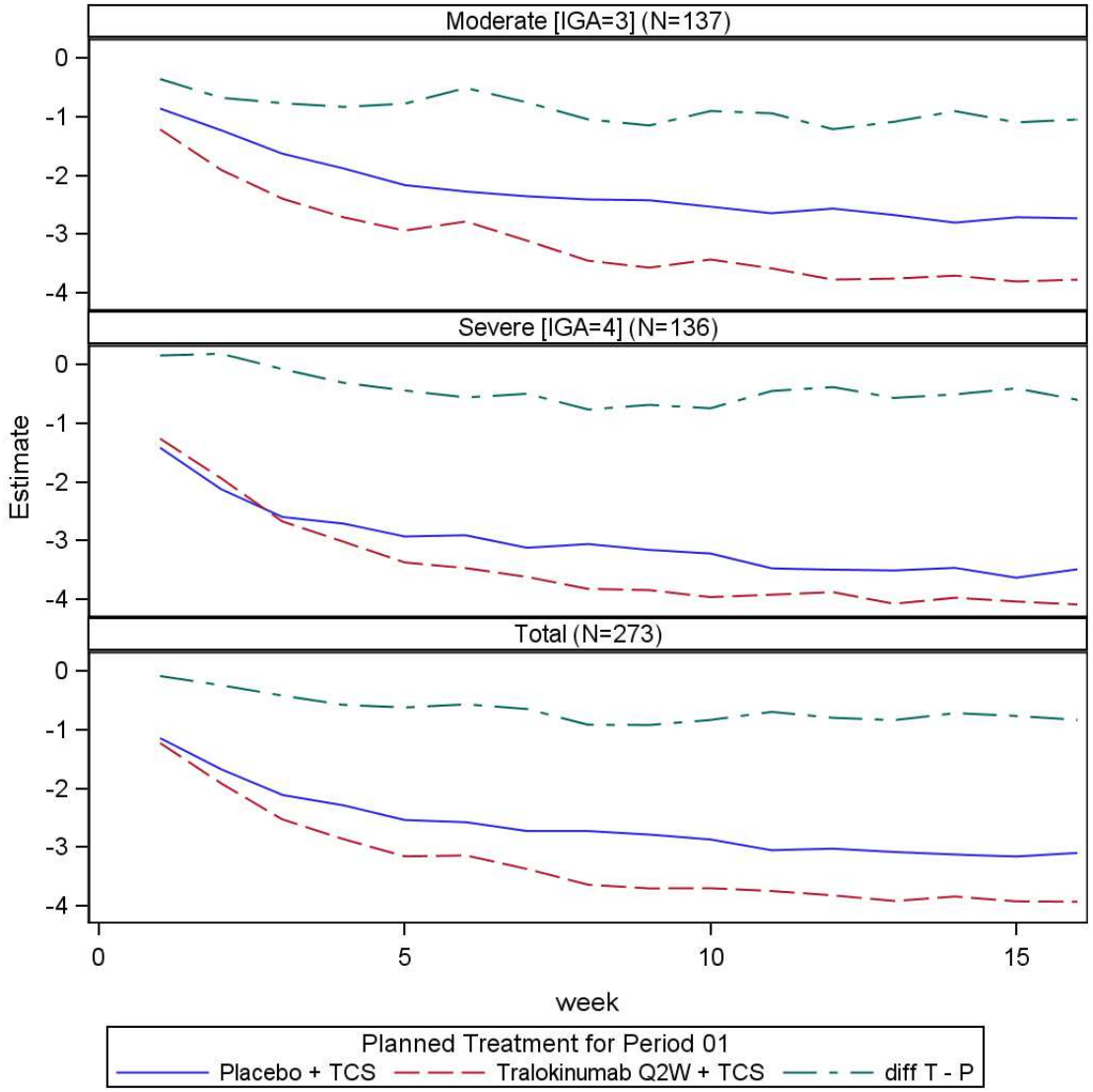
Table 1.7.403.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	59	-3.6 (2.32)	-3.47 (0.25)	64	-4.1 (2.15)	-3.98 (0.25)	-0.51 (-1.20, 0.19) [-0.23 (-0.58, 0.13)]	0.151
Week 15	60	4.0 (2.29)		64	3.5 (2.04)			
Week 15 chg	60	-3.7 (2.32)	-3.64 (0.25)	64	-4.1 (2.15)	-4.04 (0.25)	-0.41 (-1.10, 0.29) [-0.18 (-0.53, 0.17)]	0.250
Week 16	60	4.1 (2.33)		65	3.5 (1.97)			
Week 16 chg	60	-3.6 (2.30)	-3.49 (0.25)	65	-4.1 (2.09)	-4.09 (0.24)	-0.60 (-1.29, 0.09) [-0.27 (-0.63, 0.08)]	0.089

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8585
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.403.4.2: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.7.405.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)			
Week 1		135 5.8 (2.01)			136 5.2 (2.21)			
Week 1 chg		135 -1.1 (1.50)	-1.07 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.08 (-0.58, 0.42) [-0.05 (-0.29, 0.18)]	0.756
Week 2		134 5.2 (2.29)			132 4.5 (2.45)			
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.18)	-0.18 (-0.68, 0.33) [-0.09 (-0.33, 0.15)]	0.493
Week 3		133 4.7 (2.36)			131 3.9 (2.35)			
Week 3 chg		133 -2.2 (2.17)	-2.13 (0.18)		131 -2.4 (2.01)	-2.49 (0.18)	-0.36 (-0.86, 0.14) [-0.17 (-0.41, 0.07)]	0.160
Week 4		130 4.5 (2.48)			133 3.6 (2.39)			
Week 4 chg		130 -2.4 (2.23)	-2.26 (0.18)		133 -2.7 (2.06)	-2.79 (0.18)	-0.53 (-1.03, -0.03) [-0.25 (-0.49, -0.01)]	0.038
Week 5		131 4.2 (2.55)			129 3.3 (2.42)			
Week 5 chg		131 -2.7 (2.37)	-2.56 (0.18)		129 -3.0 (2.16)	-3.14 (0.18)	-0.58 (-1.08, -0.07) [-0.25 (-0.50, -0.01)]	0.024
Week 6		130 4.2 (2.52)			129 3.3 (2.42)			
Week 6 chg		130 -2.7 (2.36)	-2.53 (0.18)		129 -3.1 (2.24)	-3.20 (0.18)	-0.67 (-1.17, -0.17) [-0.29 (-0.54, -0.05)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6572
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.405.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	3.9 (2.43)		128	3.1 (2.37)		
Week 7 chg	129	-3.0 (2.38)	-2.81 (0.18)	128	-3.3 (2.28)	-3.41 (0.18)	-0.60 (-1.10, -0.10) 0.020 [-0.26 (-0.50, -0.01)]
Week 8	127	3.9 (2.46)		125	2.8 (2.29)		
Week 8 chg	127	-3.0 (2.32)	-2.79 (0.18)	125	-3.6 (2.26)	-3.65 (0.18)	-0.86 (-1.36, -0.35) <.001 [-0.37 (-0.62, -0.12)]
Week 9	127	3.8 (2.49)		127	2.6 (2.22)		
Week 9 chg	127	-3.1 (2.33)	-2.92 (0.18)	127	-3.7 (2.23)	-3.83 (0.18)	-0.91 (-1.41, -0.40) <.001 [-0.40 (-0.65, -0.15)]
Week 10	125	3.7 (2.54)		122	2.7 (2.29)		
Week 10 chg	125	-3.2 (2.40)	-3.04 (0.18)	122	-3.7 (2.29)	-3.82 (0.18)	-0.79 (-1.29, -0.28) 0.002 [-0.33 (-0.59, -0.08)]
Week 11	128	3.6 (2.46)		126	2.6 (2.22)		
Week 11 chg	128	-3.3 (2.40)	-3.15 (0.18)	126	-3.8 (2.26)	-3.89 (0.18)	-0.75 (-1.25, -0.24) 0.004 [-0.32 (-0.57, -0.07)]
Week 12	123	3.5 (2.44)		121	2.5 (2.21)		
Week 12 chg	123	-3.4 (2.45)	-3.18 (0.18)	121	-3.8 (2.38)	-4.01 (0.18)	-0.82 (-1.33, -0.31) 0.002 [-0.34 (-0.59, -0.09)]
Week 13	116	3.4 (2.40)		120	2.3 (2.13)		
Week 13 chg	116	-3.6 (2.32)	-3.32 (0.18)	120	-3.9 (2.26)	-4.05 (0.18)	-0.74 (-1.25, -0.23) 0.005 [-0.32 (-0.58, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6572
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.405.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	123	3.3 (2.42)		123	2.4 (2.18)		
Week 14 chg	123	-3.5 (2.33)	-3.36 (0.18)	123	-3.9 (2.27)	-4.03 (0.18)	-0.67 (-1.18, -0.16) 0.010 [-0.29 (-0.54, -0.04)]
Week 15	123	3.3 (2.47)		123	2.4 (2.18)		
Week 15 chg	123	-3.7 (2.35)	-3.42 (0.18)	123	-3.9 (2.35)	-4.08 (0.18)	-0.66 (-1.16, -0.15) 0.011 [-0.28 (-0.53, -0.03)]
Week 16	121	3.2 (2.40)		122	2.5 (2.17)		
Week 16 chg	121	-3.7 (2.28)	-3.41 (0.18)	122	-3.9 (2.32)	-4.06 (0.18)	-0.65 (-1.16, -0.14) 0.012 [-0.28 (-0.54, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6572
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.405.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 6.7 (1.60)		68	67 6.0 (2.00)		
Week 1		69 5.9 (1.86)			66 4.8 (2.17)		
Week 1 chg		69 -0.8 (1.35)	-0.75 (0.24)		66 -1.2 (1.59)	-1.26 (0.24)	-0.51 (-1.19, 0.17) 0.139 [-0.35 (-0.69, -0.01)]
Week 2		69 5.4 (2.12)			66 4.2 (2.36)		
Week 2 chg		69 -1.3 (1.84)	-1.19 (0.24)		66 -1.7 (1.87)	-1.89 (0.24)	-0.70 (-1.38, -0.01) 0.045 [-0.38 (-0.72, -0.03)]
Week 3		68 5.0 (2.22)			64 3.7 (2.12)		
Week 3 chg		68 -1.8 (2.01)	-1.56 (0.24)		64 -2.3 (2.00)	-2.46 (0.25)	-0.90 (-1.58, -0.21) 0.010 [-0.45 (-0.79, -0.10)]
Week 4		68 4.8 (2.43)			65 3.5 (2.36)		
Week 4 chg		68 -1.9 (2.18)	-1.77 (0.24)		65 -2.6 (2.10)	-2.73 (0.24)	-0.97 (-1.65, -0.28) 0.006 [-0.45 (-0.80, -0.11)]
Week 5		68 4.5 (2.34)			65 3.1 (2.44)		
Week 5 chg		68 -2.2 (2.19)	-2.04 (0.24)		65 -2.9 (2.13)	-3.00 (0.24)	-0.95 (-1.64, -0.27) 0.006 [-0.44 (-0.79, -0.10)]
Week 6		66 4.5 (2.33)			63 3.2 (2.49)		
Week 6 chg		66 -2.2 (2.12)	-2.07 (0.24)		63 -2.8 (2.20)	-2.97 (0.25)	-0.89 (-1.58, -0.21) 0.011 [-0.41 (-0.76, -0.06)]
Week 7		66 4.2 (2.29)			62 2.9 (2.34)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6572
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.405.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	66	-2.5 (2.16)	-2.31 (0.24)	62	-3.1 (2.18)	-3.23 (0.25)	-0.91 (-1.60, -0.23) [-0.42 (-0.77, -0.07)]	0.009
Week 8	65	4.1 (2.29)		60	2.6 (2.29)			
Week 8 chg	65	-2.6 (2.10)	-2.39 (0.24)	60	-3.5 (2.22)	-3.58 (0.25)	-1.20 (-1.88, -0.51) [-0.55 (-0.91, -0.20)]	<.001
Week 9	64	4.0 (2.28)		60	2.4 (2.02)			
Week 9 chg	64	-2.7 (2.18)	-2.55 (0.24)	60	-3.7 (2.11)	-3.84 (0.25)	-1.29 (-1.97, -0.60) [-0.60 (-0.96, -0.24)]	<.001
Week 10	65	4.0 (2.42)		59	2.5 (2.17)			
Week 10 chg	65	-2.7 (2.24)	-2.60 (0.24)	59	-3.6 (2.15)	-3.72 (0.25)	-1.12 (-1.81, -0.43) [-0.51 (-0.87, -0.15)]	0.002
Week 11	64	3.9 (2.39)		60	2.3 (2.08)			
Week 11 chg	64	-2.8 (2.29)	-2.69 (0.24)	60	-3.7 (2.14)	-3.88 (0.25)	-1.19 (-1.88, -0.50) [-0.54 (-0.89, -0.18)]	<.001
Week 12	63	3.8 (2.40)		60	2.2 (1.96)			
Week 12 chg	63	-2.9 (2.36)	-2.69 (0.24)	60	-3.8 (2.18)	-4.07 (0.25)	-1.38 (-2.07, -0.69) [-0.61 (-0.97, -0.25)]	<.001
Week 13	58	3.6 (2.31)		57	2.0 (1.94)			
Week 13 chg	58	-3.2 (2.15)	-2.88 (0.24)	57	-3.9 (2.17)	-4.04 (0.25)	-1.16 (-1.86, -0.47) [-0.54 (-0.91, -0.17)]	0.001
Week 14	64	3.6 (2.33)		59	2.1 (2.05)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6572
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.405.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	64	-3.2 (2.17)	-2.96 (0.24)	59	-3.9 (2.18)	-4.01 (0.25)	-1.05 (-1.74, -0.37) [-0.48 (-0.84, -0.13)]	0.003
Week 15	63	3.5 (2.40)		59	2.2 (1.99)			
Week 15 chg	63	-3.3 (2.22)	-2.98 (0.24)	59	-3.8 (2.16)	-4.01 (0.25)	-1.03 (-1.72, -0.34) [-0.47 (-0.83, -0.11)]	0.004
Week 16	61	3.3 (2.29)		57	2.2 (2.08)			
Week 16 chg	61	-3.5 (2.16)	-3.11 (0.24)	57	-3.9 (2.18)	-4.02 (0.25)	-0.91 (-1.60, -0.22) [-0.42 (-0.78, -0.05)]	0.010

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6572
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.405.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 7.1 (1.68)		70	70 6.6 (2.18)			
Week 1		66 5.7 (2.17)			70 5.6 (2.20)			
Week 1 chg		66 -1.4 (1.58)	-1.39 (0.27)		70 -1.0 (1.31)	-1.06 (0.26)	0.33 (-0.41, 1.07) [0.23 (-0.11, 0.56)]	0.385
Week 2		65 4.9 (2.44)			66 4.8 (2.53)			
Week 2 chg		65 -2.2 (2.05)	-2.15 (0.27)		66 -1.8 (1.74)	-1.82 (0.26)	0.33 (-0.42, 1.07) [0.17 (-0.17, 0.51)]	0.387
Week 3		65 4.3 (2.46)			67 4.1 (2.55)			
Week 3 chg		65 -2.8 (2.23)	-2.70 (0.27)		67 -2.5 (2.03)	-2.54 (0.26)	0.16 (-0.58, 0.91) [0.08 (-0.26, 0.42)]	0.666
Week 4		62 4.1 (2.51)			68 3.8 (2.42)			
Week 4 chg		62 -3.0 (2.16)	-2.76 (0.27)		68 -2.8 (2.03)	-2.86 (0.26)	-0.10 (-0.84, 0.65) [-0.05 (-0.39, 0.30)]	0.800
Week 5		63 3.9 (2.73)			64 3.5 (2.40)			
Week 5 chg		63 -3.3 (2.44)	-3.09 (0.27)		64 -3.2 (2.20)	-3.28 (0.26)	-0.19 (-0.93, 0.56) [-0.08 (-0.43, 0.27)]	0.623
Week 6		64 3.9 (2.69)			66 3.4 (2.37)			
Week 6 chg		64 -3.2 (2.50)	-3.01 (0.27)		66 -3.3 (2.27)	-3.42 (0.26)	-0.41 (-1.16, 0.33) [-0.17 (-0.52, 0.17)]	0.276
Week 7		63 3.6 (2.54)			66 3.2 (2.41)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6572
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.405.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	63	-3.5 (2.51)	-3.32 (0.27)	66	-3.5 (2.37)	-3.58 (0.26)	-0.26 (-1.00, 0.48) 0.493 [-0.11 (-0.45, 0.24)]
Week 8	62	3.7 (2.63)		65	3.1 (2.28)		
Week 8 chg	62	-3.4 (2.46)	-3.21 (0.27)	65	-3.7 (2.32)	-3.72 (0.26)	-0.51 (-1.26, 0.23) 0.177 [-0.21 (-0.56, 0.13)]
Week 9	63	3.6 (2.69)		67	2.9 (2.36)		
Week 9 chg	63	-3.5 (2.43)	-3.30 (0.27)	67	-3.7 (2.35)	-3.85 (0.26)	-0.55 (-1.29, 0.19) 0.147 [-0.23 (-0.58, 0.12)]
Week 10	60	3.4 (2.65)		63	2.9 (2.41)		
Week 10 chg	60	-3.7 (2.48)	-3.48 (0.27)	63	-3.8 (2.43)	-3.93 (0.26)	-0.45 (-1.20, 0.30) 0.238 [-0.18 (-0.54, 0.17)]
Week 11	64	3.3 (2.51)		66	2.9 (2.31)		
Week 11 chg	64	-3.8 (2.42)	-3.61 (0.27)	66	-3.8 (2.38)	-3.92 (0.26)	-0.31 (-1.06, 0.43) 0.408 [-0.13 (-0.47, 0.21)]
Week 12	60	3.2 (2.46)		61	2.8 (2.41)		
Week 12 chg	60	-3.9 (2.45)	-3.69 (0.27)	61	-3.8 (2.58)	-3.96 (0.26)	-0.28 (-1.03, 0.47) 0.469 [-0.11 (-0.47, 0.25)]
Week 13	58	3.1 (2.49)		63	2.6 (2.27)		
Week 13 chg	58	-4.0 (2.43)	-3.76 (0.27)	63	-4.0 (2.36)	-4.09 (0.26)	-0.33 (-1.08, 0.43) 0.394 [-0.14 (-0.49, 0.22)]
Week 14	59	3.1 (2.52)		64	2.6 (2.28)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6572
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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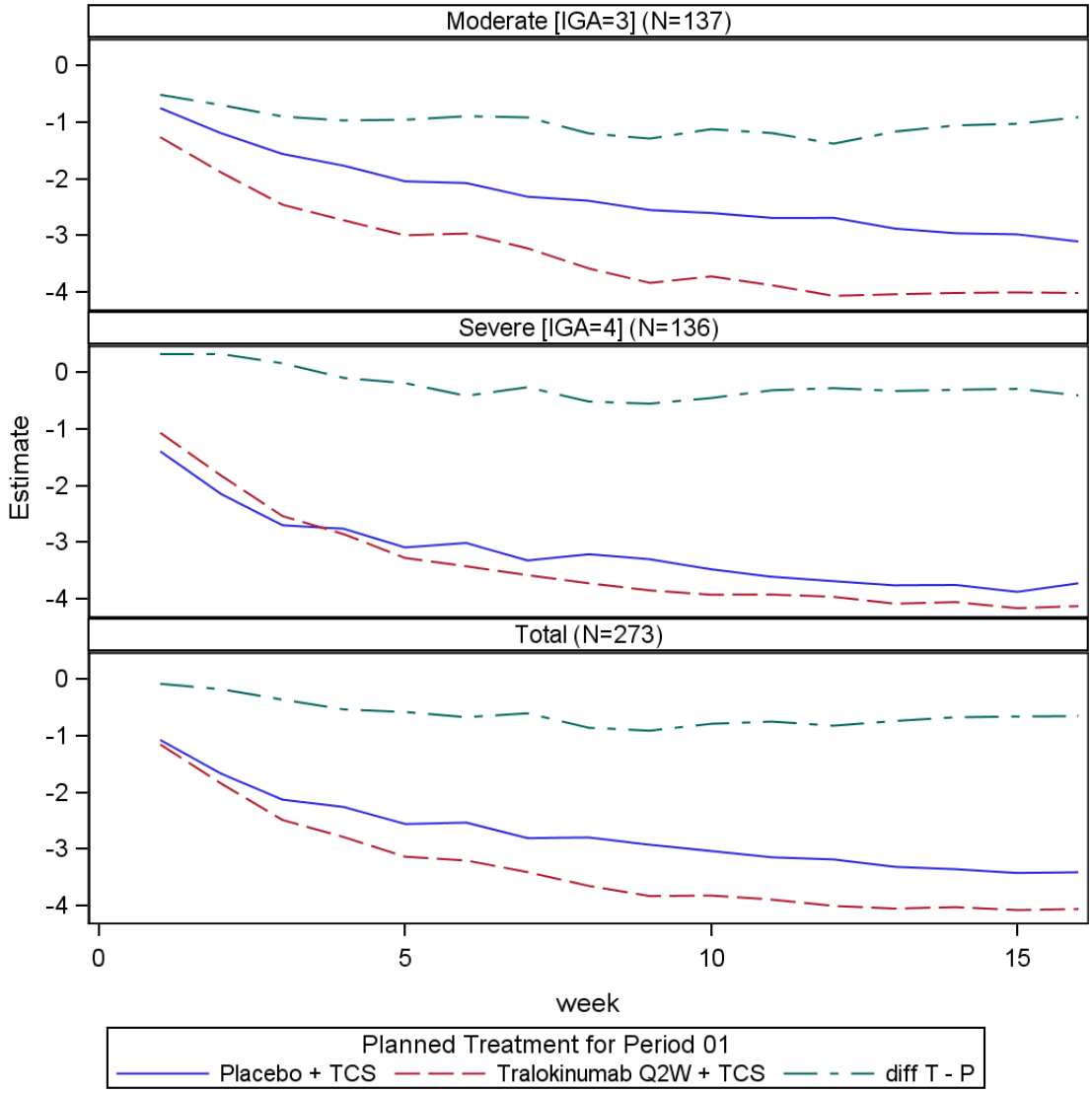
Table 1.7.405.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	59	-4.0 (2.44)	-3.75 (0.27)	64	-4.0 (2.37)	-4.06 (0.26)	-0.30 (-1.05, 0.44) [-0.13 (-0.48, 0.23)]	0.423
Week 15	60	3.1 (2.55)		64	2.6 (2.35)			
Week 15 chg	60	-4.1 (2.43)	-3.88 (0.27)	64	-4.0 (2.52)	-4.17 (0.26)	-0.29 (-1.04, 0.46) [-0.12 (-0.47, 0.24)]	0.449
Week 16	60	3.2 (2.52)		65	2.7 (2.24)			
Week 16 chg	60	-3.9 (2.39)	-3.73 (0.27)	65	-3.9 (2.46)	-4.13 (0.26)	-0.40 (-1.15, 0.34) [-0.17 (-0.52, 0.18)]	0.288

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6572
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.405.4.2: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.7.407.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.22 (1.49)		138 -20.9 (16.72)	-21.06 (1.48)	-3.84 (-7.97, 0.30) 0.069 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.25 (1.50)		137 -30.8 (17.25)	-31.00 (1.49)	-4.75 (-8.90, -0.60) 0.025 [-0.27 (-0.51, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.77 (1.50)		134 -34.3 (17.49)	-34.45 (1.49)	-7.67 (-11.8, -3.51) <.001 [-0.42 (-0.66, -0.18)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.63 (1.50)		130 -36.6 (18.48)	-36.80 (1.50)	-8.16 (-12.3, -3.99) <.001 [-0.43 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.78 (1.50)		130 -38.5 (19.49)	-38.59 (1.50)	-7.81 (-12.0, -3.63) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.51 (1.51)		128 -39.5 (18.74)	-39.57 (1.51)	-8.06 (-12.3, -3.87) <.001 [-0.42 (-0.67, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7685
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.407.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 36.0 (19.61)			127 28.3 (17.87)		
Week 14 chg		126 -34.8 (20.31)	-34.13 (1.52)		127 -41.8 (20.11)	-41.35 (1.51)	-7.22 (-11.4, -3.01) <.001 [-0.36 (-0.61, -0.11)]
Week 16		124 36.3 (18.78)			123 27.0 (16.90)		
Week 16 chg		124 -34.7 (19.94)	-33.86 (1.52)		123 -43.3 (19.46)	-42.65 (1.52)	-8.79 (-13.0, -4.57) <.001 [-0.45 (-0.70, -0.19)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7685
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.407.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 64.0 (9.94)		68	68 64.0 (8.43)			
Week 2		70 50.0 (14.14)			68 41.8 (14.97)			
Week 2 chg		70 -14.0 (15.40)	-13.84 (1.90)		68 -22.2 (14.51)	-22.16 (1.93)	-8.32 (-13.6, -2.99) [-0.56 (-0.90, -0.22)]	0.002
Week 4		69 40.4 (16.27)			68 33.3 (16.24)			
Week 4 chg		69 -23.7 (18.94)	-23.29 (1.91)		68 -30.7 (15.51)	-30.61 (1.93)	-7.31 (-12.7, -1.97) [-0.42 (-0.76, -0.08)]	0.007
Week 6		67 40.2 (15.96)			66 31.6 (15.76)			
Week 6 chg		67 -23.9 (17.48)	-23.64 (1.92)		66 -32.2 (15.06)	-32.44 (1.94)	-8.81 (-14.2, -3.43) [-0.54 (-0.89, -0.19)]	0.001
Week 8		67 38.7 (18.57)			62 28.5 (14.63)			
Week 8 chg		67 -24.9 (19.25)	-24.86 (1.92)		62 -34.8 (14.74)	-34.98 (1.97)	-10.12 (-15.5, -4.71) [-0.59 (-0.94, -0.23)]	<.001
Week 10		66 37.7 (19.29)			63 26.3 (14.54)			
Week 10 chg		66 -26.2 (21.18)	-25.88 (1.92)		63 -37.2 (14.64)	-37.06 (1.96)	-11.18 (-16.6, -5.77) [-0.61 (-0.96, -0.26)]	<.001
Week 12		65 36.5 (18.53)			61 24.2 (14.85)			
Week 12 chg		65 -27.7 (19.50)	-27.12 (1.93)		61 -39.1 (15.25)	-39.08 (1.97)	-11.96 (-17.4, -6.52) [-0.68 (-1.04, -0.32)]	<.001
Week 14		63 34.7 (18.66)			62 24.3 (15.09)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7685
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.407.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	63	-29.3 (19.73)	-29.13 (1.94)	62	-39.1 (15.48)	-39.00 (1.97)	-9.87 (-15.3, -4.43) [-0.56 (-0.91, -0.20)]	<.001
Week 16	61	34.7 (16.62)		59	23.1 (14.43)			
Week 16 chg	61	-29.5 (19.49)	-28.58 (1.95)	59	-40.5 (15.58)	-40.37 (1.98)	-11.79 (-17.3, -6.30) [-0.67 (-1.03, -0.30)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7685
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.407.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	67 77.9 (11.69)		70	70 76.2 (12.00)		
Week 2		67 56.9 (20.16)			70 56.6 (18.14)		
Week 2 chg		67 -21.1 (16.07)	-20.73 (2.30)		70 -19.6 (18.63)	-19.85 (2.25)	0.87 (-5.49, 7.23) 0.787 [0.05 (-0.28, 0.39)]
Week 4		65 47.5 (19.78)			69 44.9 (17.16)		
Week 4 chg		65 -30.3 (17.40)	-29.21 (2.32)		69 -31.0 (18.92)	-31.25 (2.26)	-2.04 (-8.44, 4.35) 0.530 [-0.11 (-0.45, 0.23)]
Week 6		65 46.7 (21.17)			68 39.9 (16.56)		
Week 6 chg		65 -31.1 (20.22)	-29.88 (2.32)		68 -36.2 (19.47)	-36.36 (2.27)	-6.48 (-12.9, -0.08) 0.047 [-0.33 (-0.67, 0.02)]
Week 8		66 44.5 (21.26)			68 37.8 (17.85)		
Week 8 chg		66 -33.2 (19.80)	-32.35 (2.31)		68 -38.3 (21.30)	-38.44 (2.27)	-6.08 (-12.5, 0.30) 0.062 [-0.30 (-0.64, 0.04)]
Week 10		65 40.8 (20.63)			67 36.2 (20.00)		
Week 10 chg		65 -36.9 (19.77)	-35.67 (2.32)		67 -39.8 (23.18)	-40.02 (2.27)	-4.35 (-10.8, 2.06) 0.182 [-0.20 (-0.54, 0.14)]
Week 12		63 40.8 (17.77)			67 36.2 (18.15)		
Week 12 chg		63 -37.4 (18.69)	-35.76 (2.33)		67 -39.9 (21.55)	-40.12 (2.27)	-4.36 (-10.8, 2.07) 0.183 [-0.22 (-0.56, 0.13)]
Week 14		63 37.3 (20.58)			65 32.1 (19.53)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7685
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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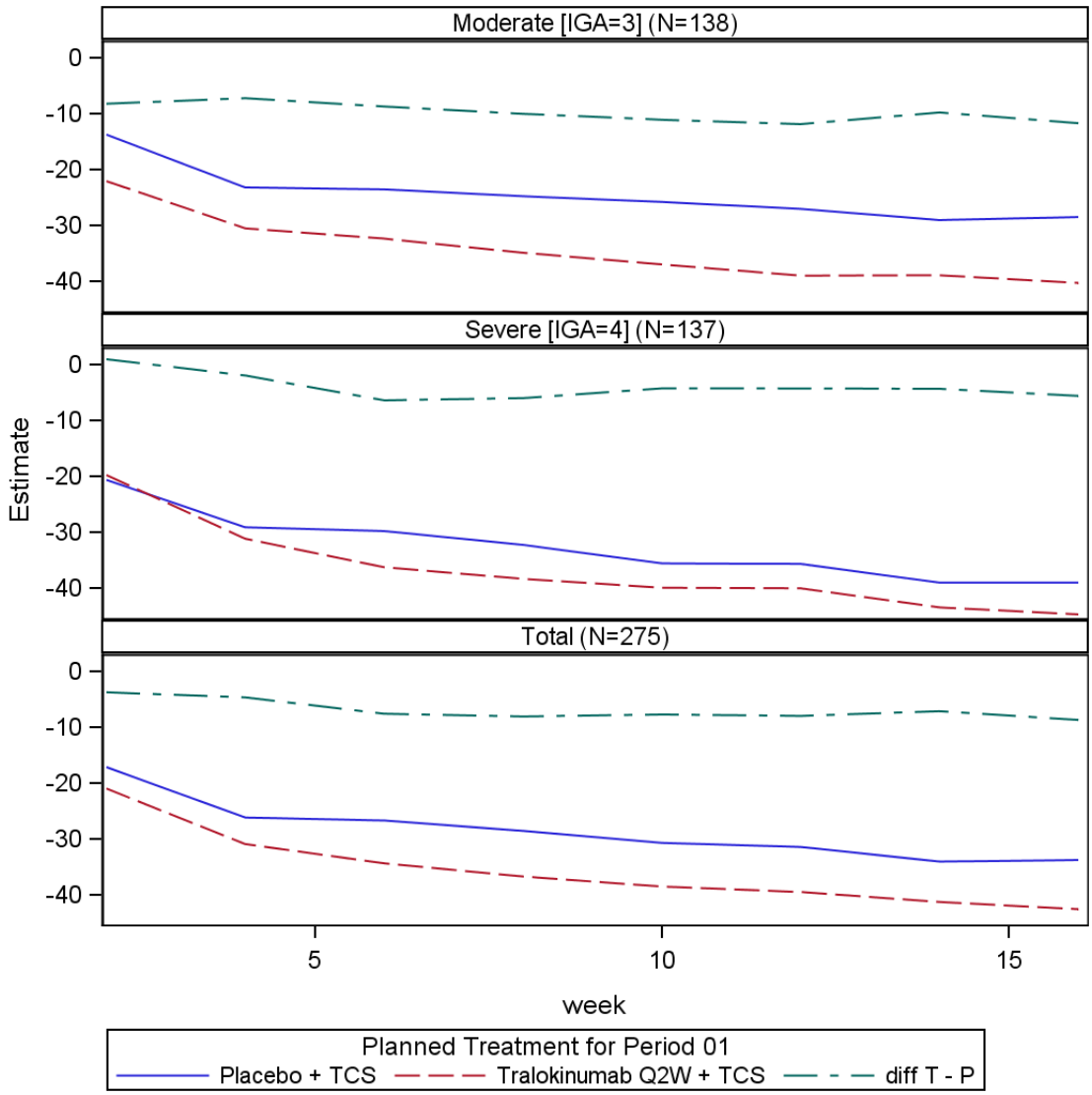
Table 1.7.407.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	63	-40.2 (19.53)	-39.11 (2.33)	65	-44.3 (23.55)	-43.54 (2.29)	-4.43 (-10.9, 2.01) [-0.20 (-0.55, 0.14)]	0.177
Week 16	63	37.9 (20.66)		64	30.5 (18.29)			
Week 16 chg	63	-39.8 (19.17)	-39.11 (2.33)	64	-45.8 (22.27)	-44.79 (2.29)	-5.69 (-12.1, 0.76) [-0.27 (-0.62, 0.08)]	0.084

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7685
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.407.4.2: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.7.409.4.1: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score									
Total									
Baseline	137	134	16.4 (6.33)		138	137	15.9 (6.53)		
Week 2		131	9.2 (6.47)			132	8.5 (6.17)		
Week 2 chg		131	-7.2 (5.73)	-7.15 (0.45)		132	-7.5 (5.92)	-7.56 (0.45)	-0.41 (-1.65, 0.84) 0.520 [-0.07 (-0.31, 0.17)]
Week 4		130	7.8 (6.27)			135	6.7 (5.98)		
Week 4 chg		130	-8.6 (6.67)	-8.32 (0.45)		135	-9.0 (6.32)	-9.14 (0.44)	-0.82 (-2.06, 0.42) 0.196 [-0.13 (-0.37, 0.12)]
Week 6		123	7.3 (6.07)			126	6.0 (5.79)		
Week 6 chg		123	-8.9 (7.23)	-8.65 (0.45)		126	-10.0 (6.75)	-9.87 (0.45)	-1.22 (-2.48, 0.03) 0.056 [-0.18 (-0.42, 0.07)]
Week 8		127	6.9 (5.70)			128	5.4 (5.11)		
Week 8 chg		127	-9.4 (6.84)	-8.97 (0.45)		128	-10.6 (6.29)	-10.39 (0.45)	-1.42 (-2.67, -0.17) 0.026 [-0.22 (-0.46, 0.03)]
Week 12		123	6.8 (5.89)			124	5.0 (3.92)		
Week 12 chg		123	-9.8 (7.26)	-9.30 (0.46)		124	-10.6 (5.77)	-10.58 (0.45)	-1.28 (-2.54, -0.02) 0.046 [-0.20 (-0.45, 0.05)]
Week 16		120	6.5 (5.63)			118	4.5 (3.88)		
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.46)		118	-11.0 (5.99)	-11.18 (0.46)	-1.50 (-2.77, -0.23) 0.021 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0221
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.409.4.1: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	68 15.0 (6.67)		68	68 15.2 (5.87)		
Week 2		67 9.8 (6.98)			65 7.5 (5.19)		
Week 2 chg		67 -5.4 (5.91)	-5.33 (0.62)		65 -7.9 (5.19)	-7.70 (0.63)	-2.37 (-4.11, -0.63) 0.008 [-0.43 (-0.77, -0.08)]
Week 4		66 8.5 (7.04)			68 6.1 (5.52)		
Week 4 chg		66 -6.6 (6.95)	-6.49 (0.63)		68 -9.1 (5.54)	-9.05 (0.62)	-2.56 (-4.29, -0.82) 0.004 [-0.41 (-0.75, -0.07)]
Week 6		63 7.2 (5.93)			65 5.9 (6.24)		
Week 6 chg		63 -7.8 (6.92)	-7.63 (0.63)		65 -9.3 (6.63)	-9.13 (0.63)	-1.50 (-3.25, 0.25) 0.093 [-0.22 (-0.57, 0.13)]
Week 8		62 7.0 (5.79)			62 4.9 (5.12)		
Week 8 chg		62 -7.9 (6.96)	-7.65 (0.63)		62 -10.5 (5.87)	-9.95 (0.63)	-2.29 (-4.06, -0.53) 0.011 [-0.36 (-0.71, -0.00)]
Week 12		63 7.0 (6.15)			60 4.4 (3.58)		
Week 12 chg		63 -8.3 (6.79)	-8.13 (0.63)		60 -10.6 (5.05)	-10.29 (0.64)	-2.16 (-3.92, -0.39) 0.017 [-0.36 (-0.72, -0.00)]
Week 16		59 6.7 (5.85)			56 4.0 (3.93)		
Week 16 chg		59 -8.2 (6.22)	-8.31 (0.64)		56 -10.6 (5.40)	-10.83 (0.65)	-2.52 (-4.31, -0.73) 0.006 [-0.43 (-0.80, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0221
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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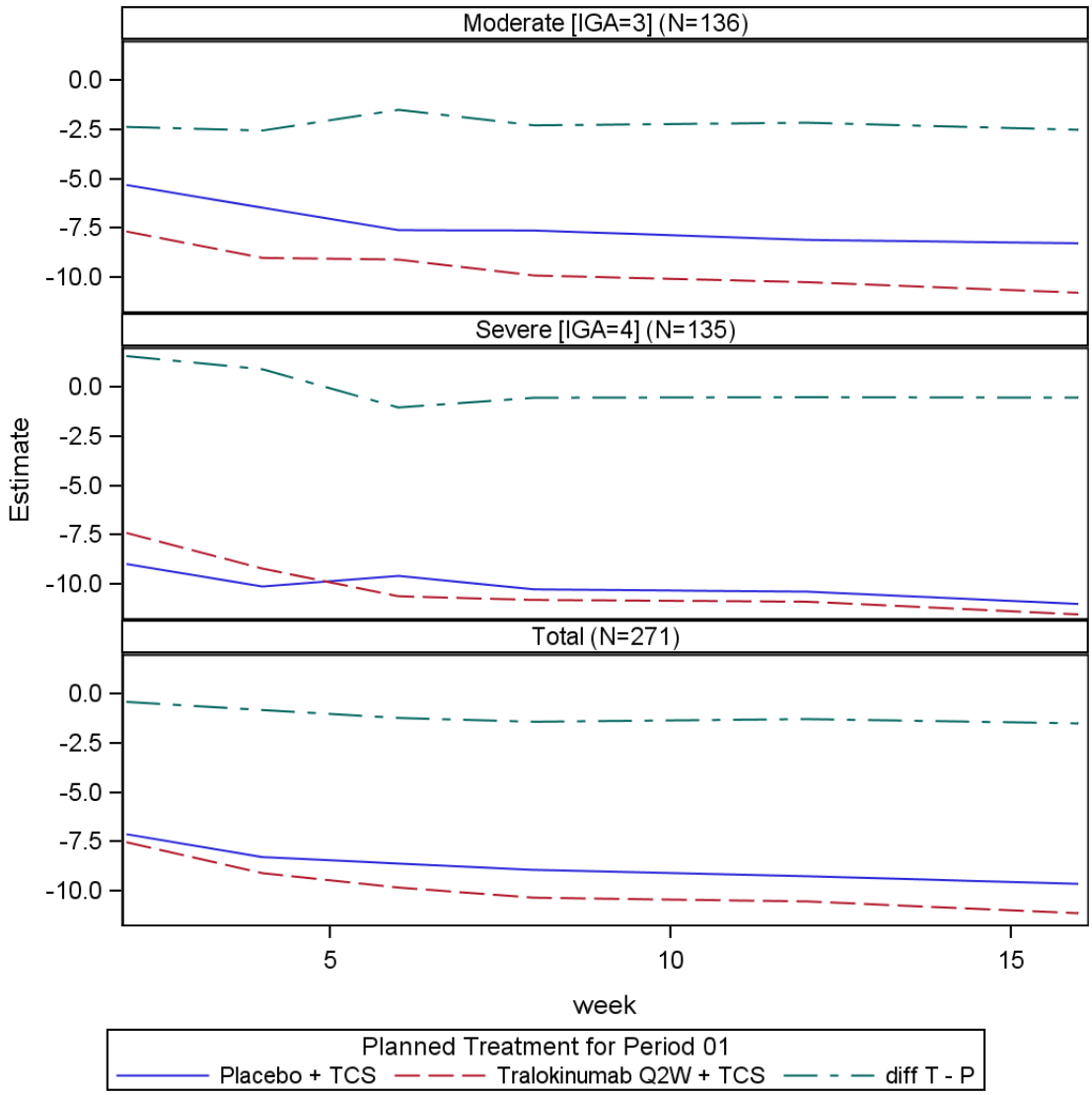
Table 1.7.409.4.1: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 17.8 (5.68)		70	69 16.5 (7.10)		
Week 2		64 8.5 (5.88)			67 9.4 (6.91)		
Week 2 chg		64 -9.2 (4.84)	-9.01 (0.64)		67 -7.2 (6.57)	-7.43 (0.62)	1.59 (-0.18, 3.35) 0.077 [0.27 (-0.07, 0.62)]
Week 4		64 7.0 (5.32)			67 7.4 (6.40)		
Week 4 chg		64 -10.7 (5.73)	-10.16 (0.64)		67 -9.0 (7.07)	-9.25 (0.62)	0.91 (-0.85, 2.68) 0.309 [0.14 (-0.20, 0.48)]
Week 6		60 7.4 (6.27)			61 6.2 (5.32)		
Week 6 chg		60 -10.1 (7.43)	-9.62 (0.65)		61 -10.7 (6.85)	-10.66 (0.64)	-1.04 (-2.83, 0.75) 0.256 [-0.14 (-0.50, 0.21)]
Week 8		65 6.8 (5.67)			66 5.9 (5.10)		
Week 8 chg		65 -10.8 (6.45)	-10.31 (0.64)		66 -10.7 (6.71)	-10.85 (0.63)	-0.54 (-2.30, 1.22) 0.548 [-0.08 (-0.42, 0.26)]
Week 12		60 6.6 (5.66)			64 5.6 (4.17)		
Week 12 chg		60 -11.3 (7.48)	-10.42 (0.65)		64 -10.7 (6.41)	-10.94 (0.63)	-0.51 (-2.30, 1.27) 0.572 [-0.07 (-0.43, 0.28)]
Week 16		61 6.3 (5.46)			62 4.9 (3.81)		
Week 16 chg		61 -11.6 (6.46)	-11.05 (0.65)		62 -11.3 (6.52)	-11.58 (0.64)	-0.53 (-2.32, 1.26) 0.557 [-0.08 (-0.44, 0.27)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0221
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 12:17 LP0162-Payer /p_mmrm3/t_t_igag_g09_46_w16.txt

Figure 1.7.409.4.2: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.7.410.4.1: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 2		130 15.1 (6.91)			130 13.5 (6.31)			
Week 2 chg		130 -5.9 (6.29)	-5.98 (0.55)		130 -7.7 (5.43)	-7.66 (0.54)	-1.69 (-3.20, -0.17)	0.029
							[-0.29 (-0.53, -0.04)]	
Week 4		130 13.8 (7.45)			133 11.6 (6.30)			
Week 4 chg		130 -7.1 (7.56)	-7.12 (0.55)		133 -9.7 (6.02)	-9.53 (0.54)	-2.40 (-3.92, -0.89)	0.002
							[-0.35 (-0.60, -0.11)]	
Week 6		123 13.5 (7.81)			124 10.9 (5.95)			
Week 6 chg		123 -7.2 (8.29)	-7.34 (0.55)		124 -10.6 (6.27)	-10.36 (0.55)	-3.02 (-4.56, -1.48)	<.001
							[-0.41 (-0.66, -0.16)]	
Week 8		127 13.1 (7.02)			126 9.9 (5.79)			
Week 8 chg		127 -7.6 (7.95)	-7.73 (0.55)		126 -11.5 (6.10)	-11.20 (0.55)	-3.47 (-5.00, -1.94)	<.001
							[-0.49 (-0.74, -0.24)]	
Week 12		123 13.0 (7.39)			122 9.2 (5.72)			
Week 12 chg		123 -8.0 (8.26)	-7.90 (0.55)		122 -12.4 (6.20)	-11.83 (0.55)	-3.93 (-5.47, -2.39)	<.001
							[-0.54 (-0.79, -0.28)]	
Week 16		120 13.0 (7.69)			116 9.1 (5.58)			
Week 16 chg		120 -8.0 (8.09)	-8.05 (0.56)		116 -12.2 (6.39)	-11.87 (0.56)	-3.82 (-5.37, -2.27)	<.001
							[-0.52 (-0.78, -0.26)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4986
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.410.4.1: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	68 20.0 (6.11)		68	68 21.3 (4.52)			
Week 2		67 15.2 (7.49)			65 13.0 (5.99)			
Week 2 chg		67 -4.9 (6.17)	-4.99 (0.76)		65 -8.3 (5.37)	-8.16 (0.76)	-3.18 (-5.30, -1.05) [-0.55 (-0.90, -0.20)]	0.004
Week 4		66 14.0 (8.17)			68 11.0 (6.01)			
Week 4 chg		66 -6.1 (7.48)	-6.30 (0.76)		68 -10.3 (5.67)	-10.08 (0.76)	-3.78 (-5.90, -1.66) [-0.57 (-0.92, -0.22)]	<.001
Week 6		63 13.0 (8.00)			65 10.2 (5.80)			
Week 6 chg		63 -6.8 (7.90)	-7.18 (0.77)		65 -11.0 (6.23)	-10.66 (0.76)	-3.48 (-5.62, -1.33) [-0.49 (-0.84, -0.14)]	0.002
Week 8		62 12.9 (6.86)			62 8.9 (5.34)			
Week 8 chg		62 -6.8 (7.20)	-7.18 (0.78)		62 -12.3 (5.72)	-11.83 (0.77)	-4.64 (-6.80, -2.48) [-0.71 (-1.08, -0.35)]	<.001
Week 12		63 12.8 (7.48)			60 8.6 (5.92)			
Week 12 chg		63 -7.4 (7.78)	-7.63 (0.77)		60 -12.9 (6.51)	-12.00 (0.78)	-4.37 (-6.54, -2.21) [-0.61 (-0.97, -0.25)]	<.001
Week 16		59 12.7 (7.53)			56 8.8 (6.03)			
Week 16 chg		59 -7.3 (7.60)	-7.71 (0.78)		56 -12.5 (6.90)	-11.80 (0.79)	-4.09 (-6.29, -1.89) [-0.56 (-0.94, -0.19)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4986
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.410.4.1: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 21.8 (5.18)		70	67 21.3 (5.71)			
Week 2		63 15.0 (6.30)			65 14.0 (6.63)			
Week 2 chg		63 -7.0 (6.27)	-6.99 (0.79)		65 -7.2 (5.46)	-7.20 (0.78)	-0.21 (-2.41, 1.98) [-0.04 (-0.38, 0.31)]	0.848
Week 4		64 13.5 (6.70)			65 12.3 (6.57)			
Week 4 chg		64 -8.1 (7.55)	-7.89 (0.79)		65 -9.0 (6.35)	-9.05 (0.78)	-1.16 (-3.35, 1.04) [-0.17 (-0.51, 0.18)]	0.300
Week 6		60 14.0 (7.63)			59 11.5 (6.09)			
Week 6 chg		60 -7.5 (8.72)	-7.44 (0.80)		59 -10.3 (6.35)	-10.10 (0.80)	-2.66 (-4.89, -0.44) [-0.35 (-0.71, 0.01)]	0.019
Week 8		65 13.3 (7.22)			64 10.9 (6.09)			
Week 8 chg		65 -8.4 (8.59)	-8.20 (0.79)		64 -10.8 (6.42)	-10.64 (0.79)	-2.45 (-4.64, -0.26) [-0.32 (-0.67, 0.03)]	0.029
Week 12		60 13.2 (7.36)			62 9.8 (5.51)			
Week 12 chg		60 -8.6 (8.76)	-8.11 (0.80)		62 -11.9 (5.89)	-11.69 (0.79)	-3.57 (-5.79, -1.36) [-0.48 (-0.84, -0.12)]	0.002
Week 16		61 13.2 (7.90)			60 9.3 (5.16)			
Week 16 chg		61 -8.7 (8.56)	-8.39 (0.80)		60 -11.9 (5.92)	-11.92 (0.80)	-3.53 (-5.75, -1.31) [-0.48 (-0.84, -0.12)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4986
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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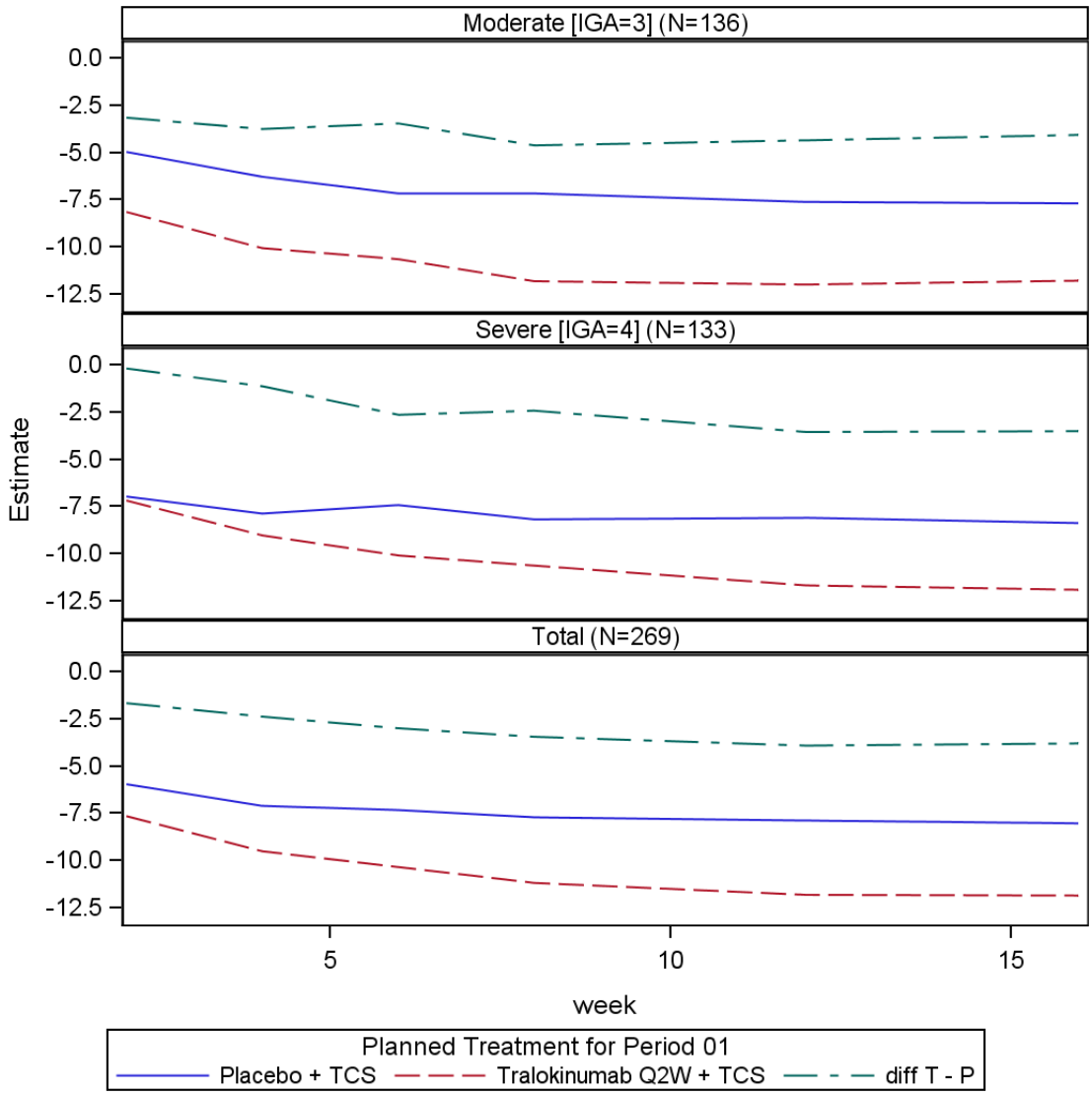
Figure 1.7.410.4.2: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 16



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 Prior CSA use, 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 1.7.414.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.60 (0.81)		138 -12.9 (10.72)	-13.33 (0.81)	-0.73 (-2.98, 1.53) 0.526 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.57 (0.81)		137 -18.8 (10.58)	-19.44 (0.81)	-1.86 (-4.13, 0.40) 0.106 [-0.17 (-0.40, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.53 (0.82)		134 -20.9 (11.93)	-21.51 (0.81)	-2.98 (-5.25, -0.71) 0.010 [-0.24 (-0.48, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.30 (0.82)		130 -22.5 (12.16)	-23.17 (0.82)	-3.88 (-6.15, -1.60) <.001 [-0.30 (-0.54, -0.05)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.61 (0.82)		130 -24.3 (11.55)	-25.02 (0.82)	-4.41 (-6.69, -2.13) <.001 [-0.34 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-21.10 (0.82)		128 -24.7 (12.40)	-25.22 (0.82)	-4.11 (-6.40, -1.83) <.001 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6315
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 16:06 LP0162-Payer /p_mmrm3/t_t_igag_g14_46_w26.txt

Table 1.7.414.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	11.2 (11.57)		127	7.0 (8.34)		
Week 14 chg	126	-22.8 (14.69)	-21.89 (0.82)	127	-25.1 (13.29)	-25.74 (0.82)	-3.85 (-6.14, -1.55) 0.001 [-0.27 (-0.52, -0.03)]
Week 16	124	10.5 (11.42)		123	6.4 (7.63)		
Week 16 chg	124	-23.8 (14.93)	-22.65 (0.83)	123	-25.9 (12.78)	-26.17 (0.83)	-3.52 (-5.82, -1.22) 0.003 [-0.25 (-0.50, -0.00)]
Week 18	116	10.7 (11.52)		115	5.9 (7.36)		
Week 18 chg	116	-23.6 (14.71)	-22.56 (0.84)	115	-26.4 (12.11)	-26.14 (0.84)	-3.58 (-5.91, -1.25) 0.003 [-0.27 (-0.52, -0.01)]
Week 20	107	10.6 (12.56)		117	5.5 (6.56)		
Week 20 chg	107	-24.1 (15.32)	-22.56 (0.85)	117	-26.9 (11.94)	-26.74 (0.84)	-4.18 (-6.53, -1.84) <.001 [-0.31 (-0.57, -0.04)]
Week 22	112	10.5 (11.17)		114	5.0 (5.93)		
Week 22 chg	112	-24.3 (14.63)	-22.40 (0.84)	114	-27.3 (12.17)	-27.13 (0.84)	-4.73 (-7.08, -2.39) <.001 [-0.35 (-0.61, -0.09)]
Week 24	112	9.9 (11.00)		117	5.3 (7.21)		
Week 24 chg	112	-24.9 (14.38)	-22.80 (0.84)	117	-27.0 (12.11)	-26.99 (0.84)	-4.19 (-6.53, -1.85) <.001 [-0.32 (-0.58, -0.06)]
Week 26	118	9.1 (10.14)		125	5.6 (7.90)		
Week 26 chg	118	-25.5 (13.74)	-23.71 (0.83)	125	-26.5 (12.83)	-27.01 (0.82)	-3.30 (-5.61, -0.99) 0.005 [-0.25 (-0.50, 0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6315
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 16:06 LP0162-Payer /p_mmrm3/t_t_igag_g14_46_w26.txt

Table 1.7.414.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 27.1 (7.27)		68	68 26.0 (5.96)		
Week 2		70 16.0 (9.13)			68 13.0 (8.66)		
Week 2 chg		70 -11.1 (10.82)	-10.79 (0.92)		68 -13.1 (8.06)	-13.48 (0.94)	-2.69 (-5.27, -0.10) 0.042 [-0.28 (-0.62, 0.05)]
Week 4		69 11.7 (8.80)			68 8.7 (7.42)		
Week 4 chg		69 -15.5 (11.32)	-15.03 (0.93)		68 -17.3 (7.88)	-17.82 (0.94)	-2.79 (-5.39, -0.20) 0.035 [-0.29 (-0.62, 0.05)]
Week 6		67 11.3 (9.02)			66 8.1 (7.87)		
Week 6 chg		67 -15.9 (10.08)	-15.62 (0.93)		66 -18.1 (8.01)	-18.40 (0.94)	-2.78 (-5.39, -0.16) 0.037 [-0.30 (-0.65, 0.04)]
Week 8		67 11.4 (10.71)			62 6.7 (6.06)		
Week 8 chg		67 -15.7 (12.14)	-15.43 (0.93)		62 -19.1 (6.75)	-19.51 (0.96)	-4.07 (-6.71, -1.44) 0.003 [-0.41 (-0.76, -0.06)]
Week 10		66 10.7 (10.29)			63 5.0 (5.22)		
Week 10 chg		66 -16.3 (12.52)	-15.95 (0.94)		63 -20.9 (6.55)	-21.26 (0.95)	-5.32 (-7.95, -2.68) <.001 [-0.53 (-0.88, -0.18)]
Week 12		65 9.9 (9.55)			61 4.6 (5.04)		
Week 12 chg		65 -17.3 (11.97)	-16.70 (0.94)		61 -21.4 (6.93)	-21.71 (0.96)	-5.01 (-7.66, -2.36) <.001 [-0.51 (-0.86, -0.15)]
Week 14		63 9.8 (9.49)			62 4.7 (5.54)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6315
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.414.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	63	-17.2 (11.53)	-17.03 (0.95)	62	-21.2 (7.38)	-21.62 (0.96)	-4.59 (-7.24, -1.94) <.001 [-0.47 (-0.83, -0.12)]
Week 16	61	9.0 (9.13)		59	4.3 (5.71)		
Week 16 chg	61	-18.1 (12.07)	-17.42 (0.95)	59	-21.8 (7.75)	-21.94 (0.97)	-4.52 (-7.19, -1.84) <.001 [-0.44 (-0.81, -0.08)]
Week 18	58	8.8 (9.18)		59	3.8 (4.45)		
Week 18 chg	58	-18.5 (11.59)	-17.74 (0.96)	59	-22.3 (7.08)	-22.33 (0.97)	-4.60 (-7.29, -1.90) <.001 [-0.48 (-0.85, -0.11)]
Week 20	56	8.4 (9.28)		58	3.5 (4.49)		
Week 20 chg	56	-18.9 (12.13)	-18.33 (0.97)	58	-22.6 (7.29)	-22.64 (0.97)	-4.30 (-7.01, -1.59) 0.002 [-0.43 (-0.80, -0.06)]
Week 22	55	8.4 (8.62)		57	4.1 (5.13)		
Week 22 chg	55	-19.3 (11.97)	-18.12 (0.98)	57	-21.9 (7.68)	-22.18 (0.98)	-4.06 (-6.78, -1.33) 0.004 [-0.41 (-0.78, -0.03)]
Week 24	53	7.3 (8.75)		58	3.4 (4.64)		
Week 24 chg	53	-20.2 (12.37)	-18.58 (0.99)	58	-22.5 (7.55)	-22.92 (0.97)	-4.34 (-7.07, -1.61) 0.002 [-0.43 (-0.80, -0.05)]
Week 26	59	6.5 (7.91)		61	3.3 (4.40)		
Week 26 chg	59	-21.1 (11.85)	-19.78 (0.96)	61	-22.6 (7.33)	-23.08 (0.96)	-3.31 (-5.99, -0.63) 0.016 [-0.34 (-0.70, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6315
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.414.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	67 40.9 (14.81)		70	70 38.0 (12.58)		
Week 2		67 26.1 (16.11)			70 25.3 (13.21)		
Week 2 chg		67 -14.8 (11.29)	-14.33 (1.34)		70 -12.7 (12.84)	-13.27 (1.31)	1.06 (-2.65, 4.77) 0.574 [0.09 (-0.25, 0.42)]
Week 4		65 19.9 (14.55)			69 17.4 (11.10)		
Week 4 chg		65 -21.1 (11.96)	-19.99 (1.35)		69 -20.3 (12.58)	-21.08 (1.32)	-1.09 (-4.81, 2.64) 0.567 [-0.09 (-0.43, 0.25)]
Week 6		65 18.3 (14.34)			68 14.2 (10.36)		
Week 6 chg		65 -22.7 (14.05)	-21.37 (1.35)		68 -23.6 (14.31)	-24.57 (1.32)	-3.21 (-6.94, 0.52) 0.092 [-0.23 (-0.57, 0.12)]
Week 8		66 16.7 (14.06)			68 12.2 (9.54)		
Week 8 chg		66 -24.2 (14.25)	-23.11 (1.34)		68 -25.6 (14.93)	-26.67 (1.32)	-3.56 (-7.28, 0.16) 0.061 [-0.24 (-0.58, 0.10)]
Week 10		65 14.3 (12.74)			67 10.1 (8.33)		
Week 10 chg		65 -26.7 (13.45)	-25.23 (1.35)		67 -27.4 (14.11)	-28.64 (1.32)	-3.42 (-7.15, 0.32) 0.073 [-0.25 (-0.59, 0.09)]
Week 12		63 14.2 (12.40)			67 10.4 (8.91)		
Week 12 chg		63 -27.2 (14.75)	-25.38 (1.35)		67 -27.7 (15.26)	-28.70 (1.32)	-3.33 (-7.07, 0.42) 0.081 [-0.22 (-0.57, 0.12)]
Week 14		63 12.7 (13.24)			65 9.2 (9.89)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6315
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.414.4.1: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	63	-28.3 (15.47)	-26.66 (1.35)	65	-28.9 (16.34)	-29.75 (1.33)	-3.09 (-6.84, 0.66) 0.106 [-0.19 (-0.54, 0.15)]
Week 16	63	12.0 (13.18)		64	8.4 (8.64)		
Week 16 chg	63	-29.2 (15.48)	-27.78 (1.35)	64	-29.6 (15.20)	-30.31 (1.33)	-2.53 (-6.28, 1.23) 0.186 [-0.16 (-0.51, 0.18)]
Week 18	58	12.6 (13.28)		56	8.0 (9.07)		
Week 18 chg	58	-28.6 (15.83)	-27.27 (1.37)	56	-30.7 (14.63)	-29.88 (1.36)	-2.60 (-6.43, 1.22) 0.181 [-0.17 (-0.54, 0.20)]
Week 20	51	13.0 (15.11)		59	7.5 (7.64)		
Week 20 chg	51	-29.7 (16.55)	-26.59 (1.41)	59	-31.2 (13.98)	-30.83 (1.35)	-4.24 (-8.09, -0.38) 0.031 [-0.28 (-0.65, 0.10)]
Week 22	57	12.6 (12.90)		57	5.9 (6.57)		
Week 22 chg	57	-29.1 (15.43)	-26.55 (1.38)	57	-32.8 (13.36)	-32.05 (1.36)	-5.50 (-9.32, -1.67) 0.005 [-0.38 (-0.75, -0.01)]
Week 24	59	12.2 (12.31)		59	7.2 (8.70)		
Week 24 chg	59	-29.0 (14.87)	-26.85 (1.37)	59	-31.5 (14.03)	-31.07 (1.35)	-4.22 (-8.02, -0.42) 0.030 [-0.29 (-0.65, 0.07)]
Week 26	59	11.6 (11.49)		64	7.8 (9.72)		
Week 26 chg	59	-30.0 (14.14)	-27.41 (1.37)	64	-30.3 (15.60)	-30.95 (1.33)	-3.54 (-7.32, 0.24) 0.066 [-0.24 (-0.59, 0.12)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6315
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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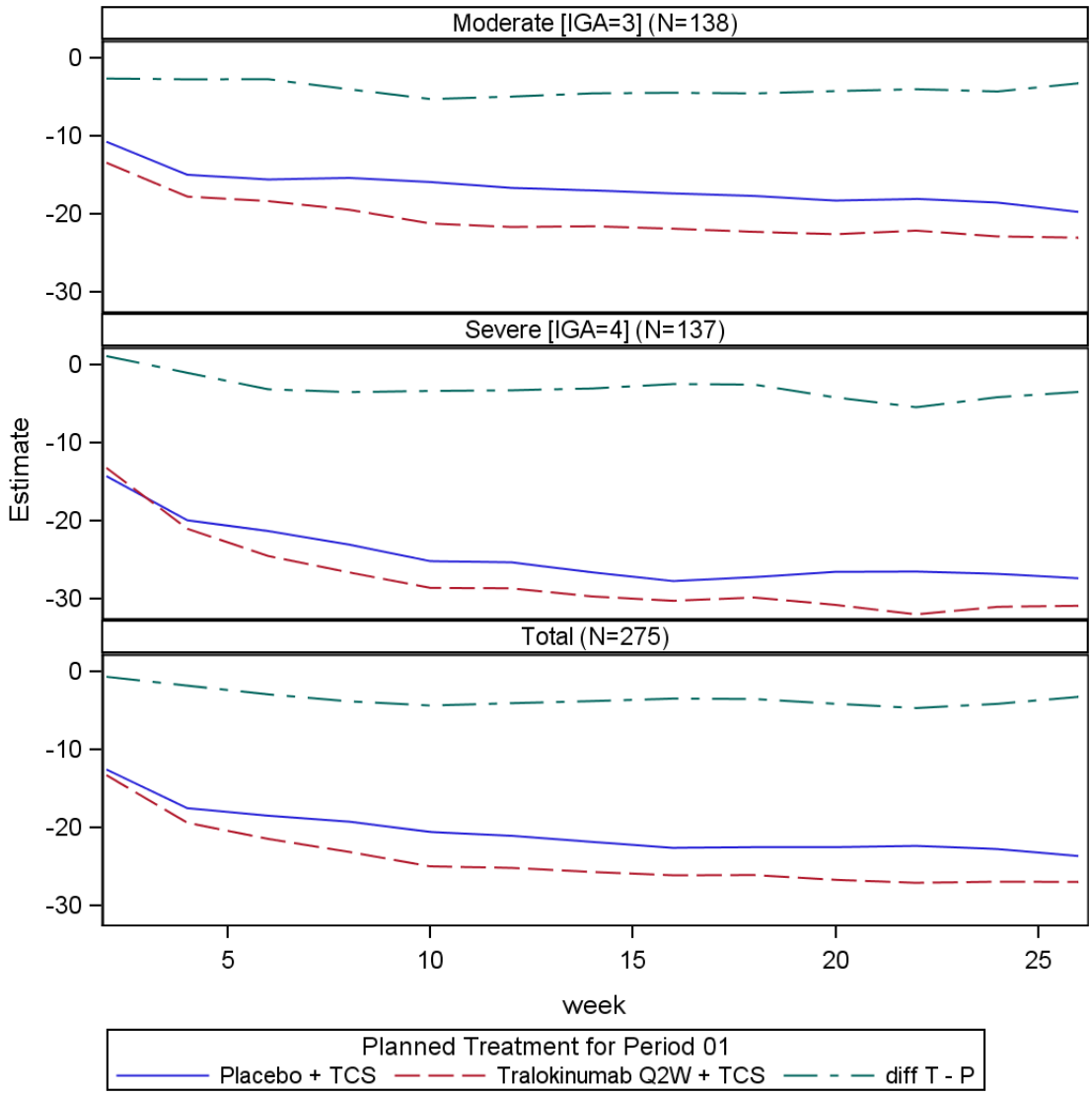
Figure 1.7.414.4.2: Total, Disease severity (IGA), change in EASI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)									
Total									
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)		
Week 1		135	6.3 (1.69)			136	6.0 (1.78)		
Week 1 chg		135	-1.1 (1.34)	-1.12 (0.18)		136	-1.2 (1.31)	-1.22 (0.18)	-0.10 (-0.60, 0.40) 0.699 [-0.07 (-0.31, 0.16)]
Week 2		134	5.8 (1.97)			132	5.4 (2.11)		
Week 2 chg		134	-1.7 (1.78)	-1.67 (0.18)		132	-1.9 (1.67)	-1.92 (0.18)	-0.24 (-0.74, 0.26) 0.338 [-0.14 (-0.38, 0.10)]
Week 3		133	5.3 (2.17)			131	4.8 (2.08)		
Week 3 chg		133	-2.2 (2.12)	-2.11 (0.18)		131	-2.5 (1.84)	-2.53 (0.18)	-0.42 (-0.92, 0.08) 0.097 [-0.21 (-0.46, 0.03)]
Week 4		130	5.1 (2.25)			133	4.4 (2.14)		
Week 4 chg		130	-2.4 (2.14)	-2.29 (0.18)		133	-2.8 (1.92)	-2.87 (0.18)	-0.58 (-1.08, -0.08) 0.023 [-0.29 (-0.53, -0.04)]
Week 5		131	4.9 (2.37)			129	4.2 (2.15)		
Week 5 chg		131	-2.6 (2.26)	-2.53 (0.18)		129	-3.1 (1.92)	-3.16 (0.18)	-0.63 (-1.13, -0.13) 0.014 [-0.30 (-0.54, -0.06)]
Week 6		130	4.8 (2.35)			129	4.2 (2.16)		
Week 6 chg		130	-2.7 (2.25)	-2.55 (0.18)		129	-3.1 (1.99)	-3.15 (0.18)	-0.61 (-1.11, -0.10) 0.018 [-0.29 (-0.53, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	4.7 (2.24)		128	4.0 (2.13)			
Week 7 chg	129	-2.8 (2.25)	-2.69 (0.18)	128	-3.3 (2.05)	-3.38 (0.18)	-0.69 (-1.19, -0.19) [-0.32 (-0.57, -0.07)]	0.007
Week 8	127	4.7 (2.32)		125	3.7 (2.10)			
Week 8 chg	127	-2.8 (2.27)	-2.69 (0.18)	125	-3.7 (1.96)	-3.65 (0.18)	-0.96 (-1.46, -0.46) [-0.45 (-0.70, -0.20)]	<.001
Week 9	127	4.6 (2.37)		127	3.6 (2.10)			
Week 9 chg	127	-2.9 (2.32)	-2.76 (0.18)	127	-3.7 (2.03)	-3.71 (0.18)	-0.95 (-1.45, -0.45) [-0.44 (-0.69, -0.19)]	<.001
Week 10	125	4.5 (2.42)		122	3.6 (2.11)			
Week 10 chg	125	-2.9 (2.39)	-2.84 (0.18)	122	-3.7 (1.93)	-3.70 (0.18)	-0.87 (-1.37, -0.36) [-0.40 (-0.65, -0.15)]	<.001
Week 11	128	4.4 (2.41)		126	3.5 (2.15)			
Week 11 chg	128	-3.1 (2.40)	-3.03 (0.18)	126	-3.7 (1.97)	-3.76 (0.18)	-0.73 (-1.23, -0.23) [-0.33 (-0.58, -0.09)]	0.004
Week 12	123	4.4 (2.36)		121	3.5 (2.08)			
Week 12 chg	123	-3.1 (2.41)	-2.99 (0.18)	121	-3.8 (2.06)	-3.82 (0.18)	-0.83 (-1.33, -0.32) [-0.37 (-0.62, -0.12)]	0.001
Week 13	116	4.3 (2.38)		120	3.3 (2.06)			
Week 13 chg	116	-3.3 (2.35)	-3.05 (0.18)	120	-4.0 (2.09)	-3.92 (0.18)	-0.87 (-1.38, -0.37) [-0.39 (-0.65, -0.14)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.11 (0.18)	123	-3.9 (2.12)	-3.85 (0.18)	-0.74 (-1.25, -0.24) [-0.33 (-0.59, -0.08)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.17 (0.18)	123	-4.0 (2.15)	-3.93 (0.18)	-0.76 (-1.26, -0.25) [-0.34 (-0.59, -0.09)]	0.003
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.09 (0.18)	122	-3.9 (2.06)	-3.95 (0.18)	-0.85 (-1.36, -0.35) [-0.39 (-0.64, -0.13)]	<.001
Week 17	121	4.3 (2.46)		121	3.4 (2.13)			
Week 17 chg	121	-3.2 (2.49)	-3.09 (0.18)	121	-3.9 (2.04)	-3.93 (0.18)	-0.84 (-1.35, -0.34) [-0.37 (-0.63, -0.12)]	0.001
Week 18	120	4.4 (2.51)		123	3.3 (2.12)			
Week 18 chg	120	-3.2 (2.46)	-3.04 (0.18)	123	-4.0 (2.11)	-3.96 (0.18)	-0.93 (-1.43, -0.42) [-0.40 (-0.66, -0.15)]	<.001
Week 19	119	4.3 (2.65)		117	3.1 (2.11)			
Week 19 chg	119	-3.3 (2.55)	-3.09 (0.18)	117	-4.2 (2.19)	-4.16 (0.18)	-1.07 (-1.58, -0.57) [-0.45 (-0.71, -0.19)]	<.001
Week 20	120	4.3 (2.68)		118	3.0 (2.02)			
Week 20 chg	120	-3.3 (2.61)	-3.08 (0.18)	118	-4.2 (2.13)	-4.13 (0.18)	-1.05 (-1.56, -0.54) [-0.44 (-0.70, -0.18)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21		118	4.2 (2.59)				115	3.0 (1.94)			
Week 21 chg		118	-3.4 (2.59)	-3.21	(0.18)		115	-4.3 (2.07)	-4.22	(0.18)	-1.01 (-1.52, -0.50) <.001 [-0.43 (-0.69, -0.17)]
Week 22		120	4.2 (2.64)				116	3.0 (1.90)			
Week 22 chg		120	-3.4 (2.64)	-3.23	(0.18)		116	-4.2 (2.06)	-4.23	(0.18)	-1.01 (-1.51, -0.50) <.001 [-0.42 (-0.68, -0.17)]
Week 23		120	4.1 (2.62)				114	3.0 (1.94)			
Week 23 chg		120	-3.5 (2.58)	-3.28	(0.18)		114	-4.3 (2.15)	-4.23	(0.18)	-0.95 (-1.46, -0.44) <.001 [-0.40 (-0.66, -0.14)]
Week 24		120	4.1 (2.52)				112	2.9 (1.92)			
Week 24 chg		120	-3.4 (2.53)	-3.26	(0.18)		112	-4.3 (2.13)	-4.28	(0.18)	-1.02 (-1.53, -0.51) <.001 [-0.43 (-0.69, -0.17)]
Week 25		114	3.8 (2.46)				115	2.9 (1.90)			
Week 25 chg		114	-3.8 (2.50)	-3.46	(0.18)		115	-4.3 (2.08)	-4.34	(0.18)	-0.88 (-1.39, -0.37) <.001 [-0.38 (-0.65, -0.12)]
Week 26		112	3.9 (2.49)				118	3.0 (1.91)			
Week 26 chg		112	-3.6 (2.56)	-3.32	(0.18)		118	-4.3 (2.11)	-4.28	(0.18)	-0.96 (-1.47, -0.45) <.001 [-0.41 (-0.67, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 7.4 (1.36)		68	67 6.9 (1.39)		
Week 1		69 6.5 (1.60)			66 5.7 (1.76)		
Week 1 chg		69 -0.9 (1.26)	-0.83 (0.25)		66 -1.2 (1.42)	-1.20 (0.26)	-0.38 (-1.08, 0.33) 0.297 [-0.28 (-0.62, 0.06)]
Week 2		69 6.1 (1.98)			66 5.1 (2.10)		
Week 2 chg		69 -1.3 (1.81)	-1.23 (0.25)		66 -1.8 (1.69)	-1.91 (0.26)	-0.68 (-1.39, 0.03) 0.060 [-0.39 (-0.73, -0.05)]
Week 3		68 5.6 (2.20)			64 4.6 (2.00)		
Week 3 chg		68 -1.8 (2.14)	-1.63 (0.25)		64 -2.3 (1.80)	-2.40 (0.26)	-0.77 (-1.49, -0.06) 0.033 [-0.39 (-0.74, -0.05)]
Week 4		68 5.4 (2.31)			65 4.3 (2.16)		
Week 4 chg		68 -2.0 (2.20)	-1.88 (0.25)		65 -2.6 (1.92)	-2.72 (0.26)	-0.84 (-1.55, -0.12) 0.021 [-0.40 (-0.75, -0.06)]
Week 5		68 5.1 (2.34)			65 4.1 (2.21)		
Week 5 chg		68 -2.3 (2.25)	-2.14 (0.25)		65 -2.9 (1.89)	-2.94 (0.26)	-0.80 (-1.51, -0.09) 0.028 [-0.38 (-0.73, -0.04)]
Week 6		66 5.0 (2.25)			63 4.2 (2.30)		
Week 6 chg		66 -2.4 (2.08)	-2.22 (0.25)		63 -2.7 (1.95)	-2.79 (0.26)	-0.57 (-1.28, 0.15) 0.118 [-0.28 (-0.63, 0.07)]
Week 7		66 4.9 (2.14)			62 3.9 (2.17)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	66	-2.5 (2.07)	-2.30 (0.25)	62	-3.1 (2.01)	-3.11 (0.26)	-0.81 (-1.52, -0.09) [-0.40 (-0.75, -0.05)]	0.027
Week 8	65	4.8 (2.14)		60	3.5 (2.18)			
Week 8 chg	65	-2.5 (2.04)	-2.36 (0.25)	60	-3.4 (1.98)	-3.46 (0.26)	-1.10 (-1.81, -0.38) [-0.54 (-0.90, -0.19)]	0.003
Week 9	64	4.9 (2.18)		60	3.5 (2.09)			
Week 9 chg	64	-2.5 (2.14)	-2.37 (0.25)	60	-3.6 (1.98)	-3.58 (0.26)	-1.21 (-1.92, -0.49) [-0.58 (-0.94, -0.22)]	0.001
Week 10	65	4.7 (2.38)		59	3.6 (2.21)			
Week 10 chg	65	-2.6 (2.33)	-2.48 (0.25)	59	-3.4 (2.00)	-3.44 (0.26)	-0.96 (-1.68, -0.25) [-0.44 (-0.80, -0.09)]	0.009
Week 11	64	4.6 (2.37)		60	3.4 (2.12)			
Week 11 chg	64	-2.7 (2.35)	-2.59 (0.25)	60	-3.5 (1.91)	-3.59 (0.26)	-0.99 (-1.71, -0.28) [-0.46 (-0.82, -0.11)]	0.007
Week 12	63	4.7 (2.43)		60	3.2 (1.95)			
Week 12 chg	63	-2.7 (2.46)	-2.51 (0.25)	60	-3.7 (1.88)	-3.78 (0.26)	-1.27 (-1.99, -0.56) [-0.58 (-0.94, -0.22)]	<.001
Week 13	58	4.6 (2.47)		57	3.1 (2.05)			
Week 13 chg	58	-2.9 (2.38)	-2.61 (0.26)	57	-3.7 (2.05)	-3.76 (0.26)	-1.15 (-1.88, -0.42) [-0.52 (-0.89, -0.15)]	0.002
Week 14	64	4.4 (2.47)		59	3.2 (2.17)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	64	-3.0 (2.33)	-2.79 (0.25)	59	-3.7 (2.08)	-3.72 (0.26)	-0.93 (-1.65, -0.21) [-0.42 (-0.78, -0.06)]	0.011
Week 15	63	4.5 (2.32)		59	3.2 (2.18)			
Week 15 chg	63	-3.0 (2.28)	-2.74 (0.25)	59	-3.8 (2.15)	-3.82 (0.26)	-1.08 (-1.80, -0.36) [-0.49 (-0.85, -0.13)]	0.003
Week 16	61	4.3 (2.26)		57	3.2 (2.15)			
Week 16 chg	61	-3.0 (2.38)	-2.72 (0.25)	57	-3.7 (2.04)	-3.80 (0.26)	-1.08 (-1.80, -0.36) [-0.49 (-0.85, -0.12)]	0.004
Week 17	62	4.4 (2.51)		58	3.0 (2.16)			
Week 17 chg	62	-3.0 (2.52)	-2.75 (0.25)	58	-3.8 (2.05)	-3.93 (0.26)	-1.18 (-1.90, -0.46) [-0.51 (-0.88, -0.15)]	0.001
Week 18	61	4.6 (2.58)		59	3.2 (2.10)			
Week 18 chg	61	-2.8 (2.45)	-2.67 (0.25)	59	-3.7 (1.96)	-3.78 (0.26)	-1.12 (-1.84, -0.40) [-0.50 (-0.87, -0.14)]	0.003
Week 19	62	4.4 (2.71)		55	2.8 (2.08)			
Week 19 chg	62	-3.0 (2.51)	-2.78 (0.25)	55	-4.0 (2.09)	-4.01 (0.26)	-1.24 (-1.96, -0.51) [-0.53 (-0.90, -0.16)]	<.001
Week 20	62	4.5 (2.71)		58	2.9 (2.13)			
Week 20 chg	62	-2.9 (2.61)	-2.69 (0.25)	58	-4.0 (2.14)	-3.93 (0.26)	-1.23 (-1.96, -0.51) [-0.52 (-0.88, -0.15)]	<.001
Week 21	63	4.3 (2.60)		54	2.8 (2.00)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	63	-3.1 (2.51)	-2.85 (0.25)	54	-4.1 (2.05)	-4.10 (0.26)	-1.25 (-1.98, -0.53) <.001 [-0.54 (-0.91, -0.17)]
Week 22	63	4.3 (2.68)		56	2.7 (1.95)		
Week 22 chg	63	-3.1 (2.60)	-2.85 (0.25)	56	-4.1 (2.04)	-4.12 (0.26)	-1.26 (-1.99, -0.54) <.001 [-0.54 (-0.90, -0.17)]
Week 23	63	4.3 (2.65)		54	2.7 (2.02)		
Week 23 chg	63	-3.2 (2.58)	-2.91 (0.25)	54	-4.2 (2.11)	-4.20 (0.26)	-1.30 (-2.03, -0.57) <.001 [-0.55 (-0.92, -0.18)]
Week 24	63	4.3 (2.50)		55	2.7 (1.97)		
Week 24 chg	63	-3.2 (2.51)	-2.88 (0.25)	55	-4.1 (2.07)	-4.25 (0.26)	-1.38 (-2.10, -0.65) <.001 [-0.59 (-0.96, -0.23)]
Week 25	58	3.9 (2.49)		56	2.7 (1.99)		
Week 25 chg	58	-3.6 (2.52)	-3.13 (0.26)	56	-4.1 (2.15)	-4.26 (0.26)	-1.13 (-1.86, -0.41) 0.002 [-0.48 (-0.86, -0.11)]
Week 26	59	4.0 (2.47)		57	2.7 (1.99)		
Week 26 chg	59	-3.4 (2.58)	-2.99 (0.26)	57	-4.1 (2.19)	-4.29 (0.26)	-1.30 (-2.02, -0.57) <.001 [-0.54 (-0.91, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 7.6 (1.38)		70	70 7.6 (1.45)		
Week 1		66 6.2 (1.79)			70 6.3 (1.77)		
Week 1 chg		66 -1.4 (1.37)	-1.42 (0.26)		70 -1.3 (1.20)	-1.26 (0.25)	0.16 (-0.55, 0.87) 0.664 [0.12 (-0.22, 0.46)]
Week 2		65 5.5 (1.93)			66 5.7 (2.08)		
Week 2 chg		65 -2.1 (1.64)	-2.13 (0.26)		66 -1.9 (1.66)	-1.94 (0.25)	0.19 (-0.52, 0.90) 0.601 [0.11 (-0.23, 0.46)]
Week 3		65 5.0 (2.10)			67 4.9 (2.16)		
Week 3 chg		65 -2.6 (2.02)	-2.60 (0.26)		67 -2.7 (1.86)	-2.68 (0.25)	-0.08 (-0.79, 0.64) 0.833 [-0.04 (-0.38, 0.30)]
Week 4		62 4.8 (2.16)			68 4.6 (2.13)		
Week 4 chg		62 -2.8 (2.00)	-2.71 (0.26)		68 -3.0 (1.91)	-3.02 (0.25)	-0.31 (-1.03, 0.40) 0.388 [-0.16 (-0.51, 0.18)]
Week 5		63 4.6 (2.40)			64 4.3 (2.09)		
Week 5 chg		63 -3.0 (2.22)	-2.93 (0.26)		64 -3.3 (1.95)	-3.36 (0.25)	-0.43 (-1.15, 0.28) 0.236 [-0.21 (-0.56, 0.14)]
Week 6		64 4.7 (2.45)			66 4.2 (2.03)		
Week 6 chg		64 -3.0 (2.39)	-2.91 (0.26)		66 -3.5 (1.97)	-3.48 (0.25)	-0.57 (-1.28, 0.15) 0.118 [-0.26 (-0.61, 0.09)]
Week 7		63 4.4 (2.34)			66 4.0 (2.10)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	63	-3.2 (2.38)	-3.11 (0.26)	66	-3.6 (2.06)	-3.63 (0.25)	-0.51 (-1.23, 0.20) [-0.23 (-0.58, 0.12)]	0.157
Week 8	62	4.5 (2.50)		65	3.8 (2.04)			
Week 8 chg	62	-3.1 (2.46)	-3.04 (0.26)	65	-3.9 (1.93)	-3.83 (0.25)	-0.79 (-1.51, -0.08) [-0.36 (-0.71, -0.01)]	0.030
Week 9	63	4.4 (2.55)		67	3.8 (2.12)			
Week 9 chg	63	-3.3 (2.45)	-3.16 (0.26)	67	-3.8 (2.07)	-3.85 (0.25)	-0.69 (-1.40, 0.03) [-0.30 (-0.65, 0.04)]	0.060
Week 10	60	4.3 (2.45)		63	3.7 (2.03)			
Week 10 chg	60	-3.3 (2.41)	-3.21 (0.26)	63	-4.0 (1.85)	-3.96 (0.25)	-0.74 (-1.46, -0.02) [-0.35 (-0.70, 0.01)]	0.043
Week 11	64	4.1 (2.44)		66	3.7 (2.18)			
Week 11 chg	64	-3.5 (2.39)	-3.48 (0.26)	66	-3.9 (2.02)	-3.93 (0.25)	-0.46 (-1.17, 0.26) [-0.21 (-0.55, 0.14)]	0.207
Week 12	60	4.0 (2.27)		61	3.8 (2.18)			
Week 12 chg	60	-3.6 (2.27)	-3.49 (0.26)	61	-3.8 (2.24)	-3.87 (0.26)	-0.38 (-1.10, 0.34) [-0.17 (-0.53, 0.19)]	0.299
Week 13	58	4.1 (2.27)		63	3.5 (2.07)			
Week 13 chg	58	-3.6 (2.28)	-3.50 (0.26)	63	-4.2 (2.12)	-4.07 (0.25)	-0.57 (-1.29, 0.15) [-0.26 (-0.62, 0.10)]	0.120
Week 14	59	4.1 (2.30)		64	3.6 (2.10)			

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Test for treatment and subgroup interaction: 0.9010
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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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	59	-3.6 (2.32)	-3.45 (0.26)	64	-4.1 (2.15)	-3.98 (0.25)	-0.53 (-1.25, 0.19) [-0.24 (-0.59, 0.12)]	0.149
Week 15	60	4.0 (2.29)		64	3.5 (2.04)			
Week 15 chg	60	-3.7 (2.32)	-3.64 (0.26)	64	-4.1 (2.15)	-4.04 (0.25)	-0.40 (-1.12, 0.32) [-0.18 (-0.53, 0.17)]	0.272
Week 16	60	4.1 (2.33)		65	3.5 (1.97)			
Week 16 chg	60	-3.6 (2.30)	-3.49 (0.26)	65	-4.1 (2.09)	-4.09 (0.25)	-0.60 (-1.32, 0.12) [-0.27 (-0.63, 0.08)]	0.100
Week 17	59	4.2 (2.43)		63	3.7 (2.06)			
Week 17 chg	59	-3.5 (2.45)	-3.43 (0.26)	63	-4.0 (2.05)	-3.95 (0.25)	-0.51 (-1.23, 0.21) [-0.23 (-0.58, 0.13)]	0.161
Week 18	59	4.2 (2.45)		64	3.4 (2.14)			
Week 18 chg	59	-3.5 (2.46)	-3.43 (0.26)	64	-4.2 (2.23)	-4.12 (0.25)	-0.69 (-1.41, 0.03) [-0.29 (-0.65, 0.06)]	0.061
Week 19	57	4.2 (2.61)		62	3.3 (2.13)			
Week 19 chg	57	-3.5 (2.59)	-3.42 (0.26)	62	-4.4 (2.28)	-4.29 (0.25)	-0.86 (-1.58, -0.14) [-0.36 (-0.72, 0.01)]	0.019
Week 20	58	4.2 (2.66)		60	3.2 (1.92)			
Week 20 chg	58	-3.6 (2.60)	-3.49 (0.26)	60	-4.4 (2.11)	-4.31 (0.26)	-0.82 (-1.54, -0.10) [-0.35 (-0.71, 0.02)]	0.026
Week 21	55	3.9 (2.60)		61	3.2 (1.87)			

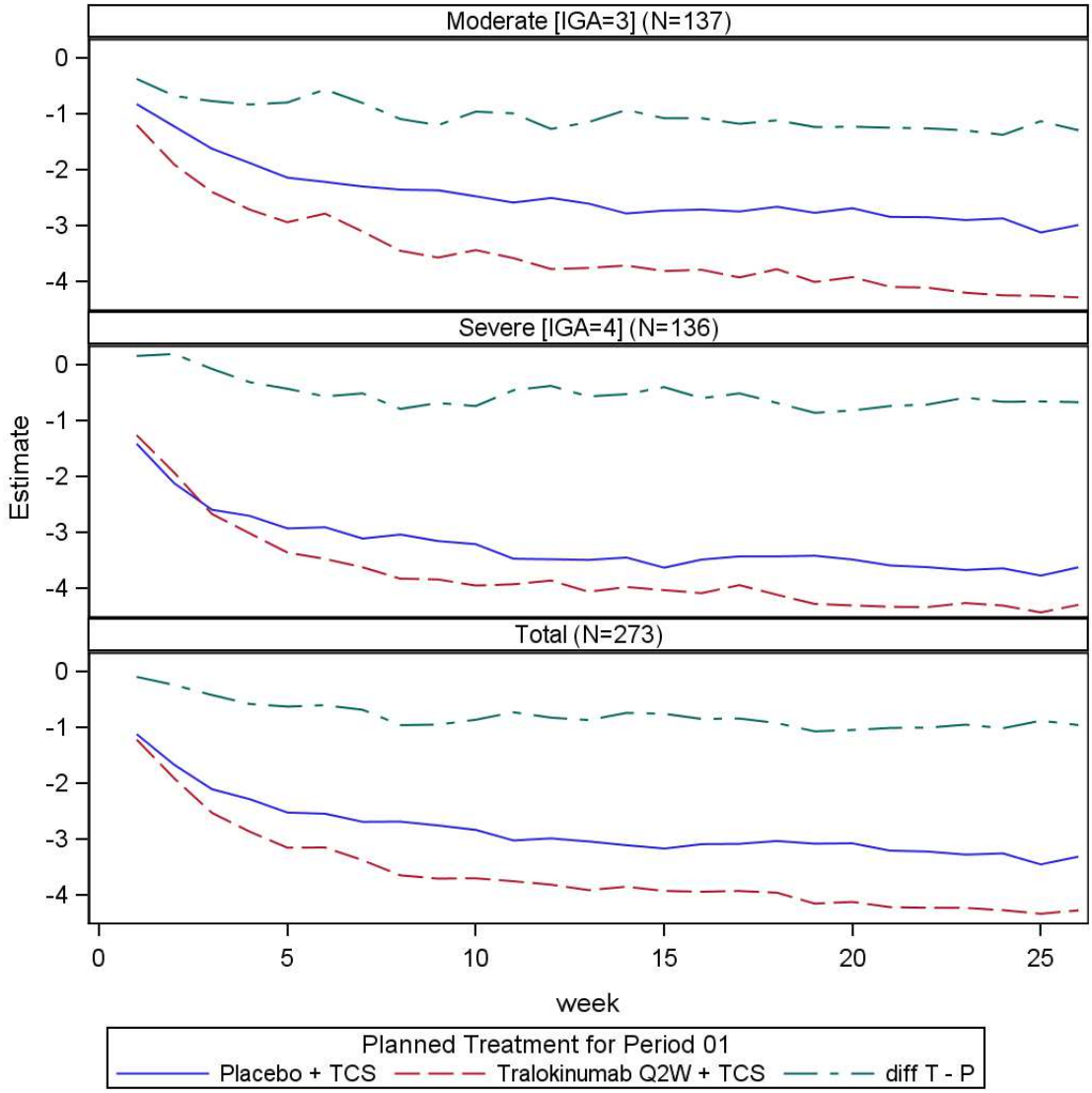
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.416.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	55	-3.7 (2.66)	-3.60 (0.26)	61	-4.4 (2.10)	-4.34 (0.26)	-0.74 (-1.46, -0.02) 0.045 [-0.31 (-0.68, 0.06)]
Week 22	57	4.0 (2.59)		60	3.2 (1.84)		
Week 22 chg	57	-3.7 (2.67)	-3.63 (0.26)	60	-4.4 (2.09)	-4.34 (0.26)	-0.71 (-1.44, 0.01) 0.053 [-0.30 (-0.66, 0.07)]
Week 23	57	3.9 (2.59)		60	3.2 (1.84)		
Week 23 chg	57	-3.8 (2.56)	-3.68 (0.26)	60	-4.4 (2.19)	-4.27 (0.26)	-0.59 (-1.31, 0.13) 0.109 [-0.25 (-0.61, 0.12)]
Week 24	57	3.9 (2.55)		57	3.2 (1.86)		
Week 24 chg	57	-3.7 (2.55)	-3.65 (0.26)	57	-4.4 (2.19)	-4.31 (0.26)	-0.67 (-1.39, 0.06) 0.072 [-0.28 (-0.65, 0.09)]
Week 25	56	3.7 (2.46)		59	3.0 (1.82)		
Week 25 chg	56	-3.9 (2.48)	-3.78 (0.26)	59	-4.5 (2.02)	-4.44 (0.26)	-0.66 (-1.38, 0.07) 0.075 [-0.29 (-0.66, 0.08)]
Week 26	53	3.9 (2.54)		61	3.2 (1.81)		
Week 26 chg	53	-3.7 (2.55)	-3.63 (0.27)	61	-4.4 (2.05)	-4.30 (0.26)	-0.67 (-1.40, 0.05) 0.070 [-0.29 (-0.66, 0.08)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9010
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.416.4.2: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)								
Total								
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)			
Week 1		135 5.8 (2.01)			136 5.2 (2.21)			
Week 1 chg		135 -1.1 (1.50)	-1.05 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.10 (-0.61, 0.42) [-0.07 (-0.30, 0.17)]	0.715
Week 2		134 5.2 (2.29)			132 4.5 (2.45)			
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.19)	-0.18 (-0.70, 0.34) [-0.09 (-0.33, 0.15)]	0.502
Week 3		133 4.7 (2.36)			131 3.9 (2.35)			
Week 3 chg		133 -2.2 (2.17)	-2.12 (0.19)		131 -2.4 (2.01)	-2.49 (0.19)	-0.37 (-0.89, 0.15) [-0.18 (-0.42, 0.07)]	0.165
Week 4		130 4.5 (2.48)			133 3.6 (2.39)			
Week 4 chg		130 -2.4 (2.23)	-2.25 (0.19)		133 -2.7 (2.06)	-2.79 (0.19)	-0.54 (-1.06, -0.02) [-0.25 (-0.50, -0.01)]	0.041
Week 5		131 4.2 (2.55)			129 3.3 (2.42)			
Week 5 chg		131 -2.7 (2.37)	-2.54 (0.19)		129 -3.0 (2.16)	-3.13 (0.19)	-0.59 (-1.11, -0.07) [-0.26 (-0.50, -0.01)]	0.027
Week 6		130 4.2 (2.52)			129 3.3 (2.42)			
Week 6 chg		130 -2.7 (2.36)	-2.50 (0.19)		129 -3.1 (2.24)	-3.21 (0.19)	-0.71 (-1.23, -0.19) [-0.31 (-0.55, -0.06)]	0.008

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	3.9 (2.43)		128	3.1 (2.37)		
Week 7 chg	129	-3.0 (2.38)	-2.77 (0.19)	128	-3.3 (2.28)	-3.41 (0.19)	-0.64 (-1.16, -0.12) 0.016 [-0.27 (-0.52, -0.03)]
Week 8	127	3.9 (2.46)		125	2.8 (2.29)		
Week 8 chg	127	-3.0 (2.32)	-2.75 (0.19)	125	-3.6 (2.26)	-3.65 (0.19)	-0.90 (-1.42, -0.38) <.001 [-0.39 (-0.64, -0.14)]
Week 9	127	3.8 (2.49)		127	2.6 (2.22)		
Week 9 chg	127	-3.1 (2.33)	-2.89 (0.19)	127	-3.7 (2.23)	-3.84 (0.19)	-0.95 (-1.47, -0.43) <.001 [-0.41 (-0.66, -0.17)]
Week 10	125	3.7 (2.54)		122	2.7 (2.29)		
Week 10 chg	125	-3.2 (2.40)	-3.00 (0.19)	122	-3.7 (2.29)	-3.82 (0.19)	-0.82 (-1.34, -0.30) 0.002 [-0.35 (-0.60, -0.10)]
Week 11	128	3.6 (2.46)		126	2.6 (2.22)		
Week 11 chg	128	-3.3 (2.40)	-3.11 (0.19)	126	-3.8 (2.26)	-3.90 (0.19)	-0.78 (-1.31, -0.26) 0.003 [-0.34 (-0.58, -0.09)]
Week 12	123	3.5 (2.44)		121	2.5 (2.21)		
Week 12 chg	123	-3.4 (2.45)	-3.14 (0.19)	121	-3.8 (2.38)	-4.00 (0.19)	-0.86 (-1.38, -0.33) 0.001 [-0.36 (-0.61, -0.10)]
Week 13	116	3.4 (2.40)		120	2.3 (2.13)		
Week 13 chg	116	-3.6 (2.32)	-3.27 (0.19)	120	-3.9 (2.26)	-4.04 (0.19)	-0.77 (-1.30, -0.25) 0.004 [-0.34 (-0.59, -0.08)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	123	3.3 (2.42)		123	2.4 (2.18)		
Week 14 chg	123	-3.5 (2.33)	-3.34 (0.19)	123	-3.9 (2.27)	-4.04 (0.19)	-0.70 (-1.22, -0.18) 0.009 [-0.30 (-0.56, -0.05)]
Week 15	123	3.3 (2.47)		123	2.4 (2.18)		
Week 15 chg	123	-3.7 (2.35)	-3.43 (0.19)	123	-3.9 (2.35)	-4.08 (0.19)	-0.65 (-1.17, -0.12) 0.015 [-0.28 (-0.53, -0.02)]
Week 16	121	3.2 (2.40)		122	2.5 (2.17)		
Week 16 chg	121	-3.7 (2.28)	-3.40 (0.19)	122	-3.9 (2.32)	-4.07 (0.19)	-0.67 (-1.20, -0.15) 0.012 [-0.29 (-0.55, -0.04)]
Week 17	121	3.4 (2.55)		121	2.4 (2.30)		
Week 17 chg	121	-3.6 (2.46)	-3.34 (0.19)	121	-4.0 (2.36)	-4.10 (0.19)	-0.76 (-1.28, -0.23) 0.005 [-0.31 (-0.57, -0.06)]
Week 18	120	3.4 (2.65)		123	2.3 (2.24)		
Week 18 chg	120	-3.6 (2.51)	-3.35 (0.19)	123	-4.0 (2.40)	-4.15 (0.19)	-0.79 (-1.31, -0.27) 0.003 [-0.32 (-0.58, -0.07)]
Week 19	119	3.3 (2.75)		117	2.2 (2.22)		
Week 19 chg	119	-3.7 (2.57)	-3.42 (0.19)	117	-4.1 (2.46)	-4.23 (0.19)	-0.81 (-1.33, -0.28) 0.003 [-0.32 (-0.58, -0.06)]
Week 20	120	3.4 (2.78)		118	2.2 (2.12)		
Week 20 chg	120	-3.6 (2.63)	-3.32 (0.19)	118	-4.1 (2.42)	-4.18 (0.19)	-0.87 (-1.39, -0.34) 0.001 [-0.34 (-0.60, -0.09)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 21	118	3.2 (2.67)		115	2.1 (2.04)			
Week 21 chg	118	-3.8 (2.62)	-3.49 (0.19)	115	-4.2 (2.37)	-4.32 (0.19)	-0.83 (-1.36, -0.30) [-0.33 (-0.59, -0.07)]	0.002
Week 22	120	3.3 (2.72)		116	2.0 (1.98)			
Week 22 chg	120	-3.7 (2.65)	-3.37 (0.19)	116	-4.3 (2.35)	-4.38 (0.19)	-1.00 (-1.53, -0.48) [-0.40 (-0.66, -0.14)]	<.001
Week 23	120	3.2 (2.64)		114	2.0 (2.02)			
Week 23 chg	120	-3.7 (2.56)	-3.45 (0.19)	114	-4.2 (2.44)	-4.35 (0.19)	-0.90 (-1.43, -0.37) [-0.36 (-0.62, -0.10)]	<.001
Week 24	120	3.2 (2.59)		112	2.0 (1.91)			
Week 24 chg	120	-3.8 (2.57)	-3.52 (0.19)	112	-4.2 (2.37)	-4.38 (0.19)	-0.86 (-1.39, -0.34) [-0.35 (-0.61, -0.09)]	0.001
Week 25	114	2.8 (2.49)		115	2.0 (1.97)			
Week 25 chg	114	-4.1 (2.53)	-3.71 (0.19)	115	-4.3 (2.44)	-4.41 (0.19)	-0.70 (-1.23, -0.17) [-0.28 (-0.54, -0.02)]	0.010
Week 26	112	2.9 (2.50)		118	2.1 (1.98)			
Week 26 chg	112	-4.0 (2.55)	-3.62 (0.19)	118	-4.2 (2.48)	-4.34 (0.19)	-0.72 (-1.25, -0.19) [-0.29 (-0.55, -0.03)]	0.008

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 6.7 (1.60)		68	67 6.0 (2.00)		
Week 1		69 5.9 (1.86)			66 4.8 (2.17)		
Week 1 chg		69 -0.8 (1.35)	-0.71 (0.25)		66 -1.2 (1.59)	-1.25 (0.25)	-0.54 (-1.24, 0.17) 0.134 [-0.36 (-0.70, -0.02)]
Week 2		69 5.4 (2.12)			66 4.2 (2.36)		
Week 2 chg		69 -1.3 (1.84)	-1.19 (0.25)		66 -1.7 (1.87)	-1.90 (0.25)	-0.70 (-1.41, 0.00) 0.050 [-0.38 (-0.72, -0.04)]
Week 3		68 5.0 (2.22)			64 3.7 (2.12)		
Week 3 chg		68 -1.8 (2.01)	-1.56 (0.25)		64 -2.3 (2.00)	-2.46 (0.25)	-0.90 (-1.61, -0.20) 0.012 [-0.45 (-0.80, -0.11)]
Week 4		68 4.8 (2.43)			65 3.5 (2.36)		
Week 4 chg		68 -1.9 (2.18)	-1.77 (0.25)		65 -2.6 (2.10)	-2.74 (0.25)	-0.97 (-1.68, -0.27) 0.007 [-0.45 (-0.80, -0.11)]
Week 5		68 4.5 (2.34)			65 3.1 (2.44)		
Week 5 chg		68 -2.2 (2.19)	-2.02 (0.25)		65 -2.9 (2.13)	-3.00 (0.25)	-0.98 (-1.68, -0.27) 0.007 [-0.45 (-0.80, -0.11)]
Week 6		66 4.5 (2.33)			63 3.2 (2.49)		
Week 6 chg		66 -2.2 (2.12)	-2.01 (0.25)		63 -2.8 (2.20)	-2.97 (0.25)	-0.96 (-1.67, -0.25) 0.008 [-0.44 (-0.79, -0.09)]
Week 7		66 4.2 (2.29)			62 2.9 (2.34)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	66	-2.5 (2.16)	-2.25 (0.25)	62	-3.1 (2.18)	-3.22 (0.25)	-0.97 (-1.68, -0.26) [-0.45 (-0.80, -0.10)]	0.007
Week 8		65 4.1 (2.29)			60 2.6 (2.29)			
Week 8 chg	65	-2.6 (2.10)	-2.33 (0.25)	60	-3.5 (2.22)	-3.58 (0.26)	-1.25 (-1.96, -0.54) [-0.58 (-0.94, -0.22)]	<.001
Week 9		64 4.0 (2.28)			60 2.4 (2.02)			
Week 9 chg	64	-2.7 (2.18)	-2.49 (0.25)	60	-3.7 (2.11)	-3.84 (0.26)	-1.35 (-2.06, -0.64) [-0.63 (-0.99, -0.27)]	<.001
Week 10		65 4.0 (2.42)			59 2.5 (2.17)			
Week 10 chg	65	-2.7 (2.24)	-2.54 (0.25)	59	-3.6 (2.15)	-3.72 (0.26)	-1.18 (-1.89, -0.47) [-0.54 (-0.90, -0.18)]	0.001
Week 11		64 3.9 (2.39)			60 2.3 (2.08)			
Week 11 chg	64	-2.8 (2.29)	-2.63 (0.25)	60	-3.7 (2.14)	-3.89 (0.26)	-1.26 (-1.97, -0.55) [-0.57 (-0.92, -0.21)]	<.001
Week 12		63 3.8 (2.40)			60 2.2 (1.96)			
Week 12 chg	63	-2.9 (2.36)	-2.62 (0.25)	60	-3.8 (2.18)	-4.08 (0.26)	-1.45 (-2.17, -0.74) [-0.64 (-1.00, -0.28)]	<.001
Week 13		58 3.6 (2.31)			57 2.0 (1.94)			
Week 13 chg	58	-3.2 (2.15)	-2.80 (0.25)	57	-3.9 (2.17)	-4.04 (0.26)	-1.24 (-1.96, -0.52) [-0.57 (-0.95, -0.20)]	<.001
Week 14		64 3.6 (2.33)			59 2.1 (2.05)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	64	-3.2 (2.17)	-2.94 (0.25)	59	-3.9 (2.18)	-4.02 (0.26)	-1.08 (-1.79, -0.37) [-0.50 (-0.86, -0.14)]	0.003
Week 15	63	3.5 (2.40)		59	2.2 (1.99)			
Week 15 chg	63	-3.3 (2.22)	-3.00 (0.25)	59	-3.8 (2.16)	-4.01 (0.26)	-1.01 (-1.72, -0.29) [-0.46 (-0.82, -0.10)]	0.006
Week 16	61	3.3 (2.29)		57	2.2 (2.08)			
Week 16 chg	61	-3.5 (2.16)	-3.08 (0.25)	57	-3.9 (2.18)	-4.03 (0.26)	-0.95 (-1.66, -0.23) [-0.44 (-0.80, -0.07)]	0.010
Week 17	62	3.4 (2.46)		58	2.0 (2.03)			
Week 17 chg	62	-3.3 (2.33)	-3.01 (0.25)	58	-4.0 (2.14)	-4.21 (0.26)	-1.20 (-1.91, -0.48) [-0.53 (-0.90, -0.17)]	0.001
Week 18	61	3.5 (2.67)		59	2.0 (1.92)			
Week 18 chg	61	-3.2 (2.43)	-2.94 (0.25)	59	-4.0 (2.09)	-4.19 (0.26)	-1.25 (-1.96, -0.54) [-0.55 (-0.91, -0.19)]	<.001
Week 19	62	3.4 (2.78)		55	1.8 (1.94)			
Week 19 chg	62	-3.4 (2.47)	-3.05 (0.25)	55	-4.1 (2.30)	-4.27 (0.26)	-1.22 (-1.94, -0.50) [-0.51 (-0.88, -0.14)]	<.001
Week 20	62	3.6 (2.80)		58	2.0 (2.00)			
Week 20 chg	62	-3.1 (2.56)	-2.85 (0.25)	58	-4.0 (2.33)	-4.09 (0.26)	-1.24 (-1.96, -0.53) [-0.51 (-0.87, -0.14)]	<.001
Week 21	63	3.4 (2.63)		54	1.9 (1.95)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 21 chg	63	-3.4 (2.46)	-3.12 (0.25)	54	-4.2 (2.26)	-4.25 (0.26)	-1.13 (-1.85, -0.41) [-0.48 (-0.85, -0.11)]	0.002
Week 22	63	3.5 (2.67)		56	1.8 (1.89)			
Week 22 chg	63	-3.3 (2.47)	-2.97 (0.25)	56	-4.2 (2.26)	-4.29 (0.26)	-1.32 (-2.04, -0.61) [-0.56 (-0.92, -0.19)]	<.001
Week 23	63	3.5 (2.55)		54	1.8 (1.86)			
Week 23 chg	63	-3.4 (2.43)	-3.03 (0.25)	54	-4.2 (2.28)	-4.34 (0.26)	-1.31 (-2.02, -0.59) [-0.55 (-0.92, -0.18)]	<.001
Week 24	63	3.4 (2.52)		55	1.7 (1.63)			
Week 24 chg	63	-3.4 (2.46)	-3.09 (0.25)	55	-4.2 (2.15)	-4.43 (0.26)	-1.34 (-2.05, -0.62) [-0.58 (-0.94, -0.21)]	<.001
Week 25	58	2.9 (2.35)		56	1.8 (1.86)			
Week 25 chg	58	-3.9 (2.35)	-3.38 (0.25)	56	-4.2 (2.31)	-4.41 (0.26)	-1.03 (-1.75, -0.31) [-0.44 (-0.81, -0.07)]	0.005
Week 26	59	2.9 (2.30)		57	1.8 (1.93)			
Week 26 chg	59	-3.8 (2.33)	-3.34 (0.25)	57	-4.1 (2.45)	-4.36 (0.26)	-1.02 (-1.74, -0.30) [-0.43 (-0.79, -0.06)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 7.1 (1.68)		70	70 6.6 (2.18)			
Week 1		66 5.7 (2.17)			70 5.6 (2.20)			
Week 1 chg		66 -1.4 (1.58)	-1.39 (0.28)		70 -1.0 (1.31)	-1.07 (0.27)	0.32 (-0.44, 1.09) [0.22 (-0.11, 0.56)]	0.402
Week 2		65 4.9 (2.44)			66 4.8 (2.53)			
Week 2 chg		65 -2.2 (2.05)	-2.15 (0.28)		66 -1.8 (1.74)	-1.82 (0.27)	0.33 (-0.43, 1.10) [0.18 (-0.17, 0.52)]	0.393
Week 3		65 4.3 (2.46)			67 4.1 (2.55)			
Week 3 chg		65 -2.8 (2.23)	-2.70 (0.28)		67 -2.5 (2.03)	-2.54 (0.27)	0.16 (-0.60, 0.93) [0.08 (-0.27, 0.42)]	0.679
Week 4		62 4.1 (2.51)			68 3.8 (2.42)			
Week 4 chg		62 -3.0 (2.16)	-2.75 (0.28)		68 -2.8 (2.03)	-2.86 (0.27)	-0.10 (-0.87, 0.66) [-0.05 (-0.39, 0.29)]	0.791
Week 5		63 3.9 (2.73)			64 3.5 (2.40)			
Week 5 chg		63 -3.3 (2.44)	-3.09 (0.28)		64 -3.2 (2.20)	-3.27 (0.27)	-0.18 (-0.95, 0.59) [-0.08 (-0.42, 0.27)]	0.650
Week 6		64 3.9 (2.69)			66 3.4 (2.37)			
Week 6 chg		64 -3.2 (2.50)	-3.01 (0.28)		66 -3.3 (2.27)	-3.43 (0.27)	-0.41 (-1.18, 0.35) [-0.17 (-0.52, 0.17)]	0.288
Week 7		63 3.6 (2.54)			66 3.2 (2.41)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	63	-3.5 (2.51)	-3.31 (0.28)	66	-3.5 (2.37)	-3.58 (0.27)	-0.27 (-1.04, 0.50) 0.487 [-0.11 (-0.46, 0.23)]
Week 8	62	3.7 (2.63)		65	3.1 (2.28)		
Week 8 chg	62	-3.4 (2.46)	-3.19 (0.28)	65	-3.7 (2.32)	-3.73 (0.27)	-0.54 (-1.31, 0.23) 0.171 [-0.22 (-0.57, 0.12)]
Week 9	63	3.6 (2.69)		67	2.9 (2.36)		
Week 9 chg	63	-3.5 (2.43)	-3.30 (0.28)	67	-3.7 (2.35)	-3.85 (0.27)	-0.55 (-1.32, 0.22) 0.158 [-0.23 (-0.58, 0.11)]
Week 10	60	3.4 (2.65)		63	2.9 (2.41)		
Week 10 chg	60	-3.7 (2.48)	-3.47 (0.28)	63	-3.8 (2.43)	-3.92 (0.27)	-0.45 (-1.22, 0.32) 0.253 [-0.18 (-0.54, 0.17)]
Week 11	64	3.3 (2.51)		66	2.9 (2.31)		
Week 11 chg	64	-3.8 (2.42)	-3.61 (0.28)	66	-3.8 (2.38)	-3.92 (0.27)	-0.32 (-1.08, 0.45) 0.418 [-0.13 (-0.48, 0.21)]
Week 12	60	3.2 (2.46)		61	2.8 (2.41)		
Week 12 chg	60	-3.9 (2.45)	-3.67 (0.28)	61	-3.8 (2.58)	-3.95 (0.27)	-0.27 (-1.05, 0.50) 0.488 [-0.11 (-0.47, 0.25)]
Week 13	58	3.1 (2.49)		63	2.6 (2.27)		
Week 13 chg	58	-4.0 (2.43)	-3.75 (0.28)	63	-4.0 (2.36)	-4.07 (0.27)	-0.32 (-1.09, 0.46) 0.418 [-0.13 (-0.49, 0.22)]
Week 14	59	3.1 (2.52)		64	2.6 (2.28)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	59	-4.0 (2.44)	-3.74 (0.28)	64	-4.0 (2.37)	-4.07 (0.27)	-0.33 (-1.10, 0.44) 0.403 [-0.14 (-0.49, 0.22)]
Week 15	60	3.1 (2.55)		64	2.6 (2.35)		
Week 15 chg	60	-4.1 (2.43)	-3.88 (0.28)	64	-4.0 (2.52)	-4.16 (0.27)	-0.29 (-1.06, 0.49) 0.467 [-0.12 (-0.47, 0.24)]
Week 16	60	3.2 (2.52)		65	2.7 (2.24)		
Week 16 chg	60	-3.9 (2.39)	-3.72 (0.28)	65	-3.9 (2.46)	-4.13 (0.27)	-0.41 (-1.18, 0.36) 0.299 [-0.17 (-0.52, 0.18)]
Week 17	59	3.3 (2.65)		63	2.8 (2.47)		
Week 17 chg	59	-3.9 (2.58)	-3.67 (0.28)	63	-3.9 (2.56)	-4.02 (0.27)	-0.35 (-1.12, 0.43) 0.378 [-0.14 (-0.49, 0.22)]
Week 18	59	3.3 (2.63)		64	2.6 (2.48)		
Week 18 chg	59	-4.0 (2.54)	-3.78 (0.28)	64	-4.0 (2.67)	-4.13 (0.27)	-0.34 (-1.12, 0.43) 0.380 [-0.13 (-0.49, 0.22)]
Week 19	57	3.2 (2.73)		62	2.5 (2.42)		
Week 19 chg	57	-4.1 (2.65)	-3.80 (0.28)	62	-4.1 (2.61)	-4.21 (0.27)	-0.41 (-1.19, 0.36) 0.294 [-0.16 (-0.52, 0.20)]
Week 20	58	3.2 (2.75)		60	2.3 (2.24)		
Week 20 chg	58	-4.1 (2.65)	-3.80 (0.28)	60	-4.1 (2.52)	-4.28 (0.27)	-0.49 (-1.27, 0.29) 0.219 [-0.19 (-0.55, 0.17)]
Week 21	55	3.0 (2.72)		61	2.3 (2.11)		

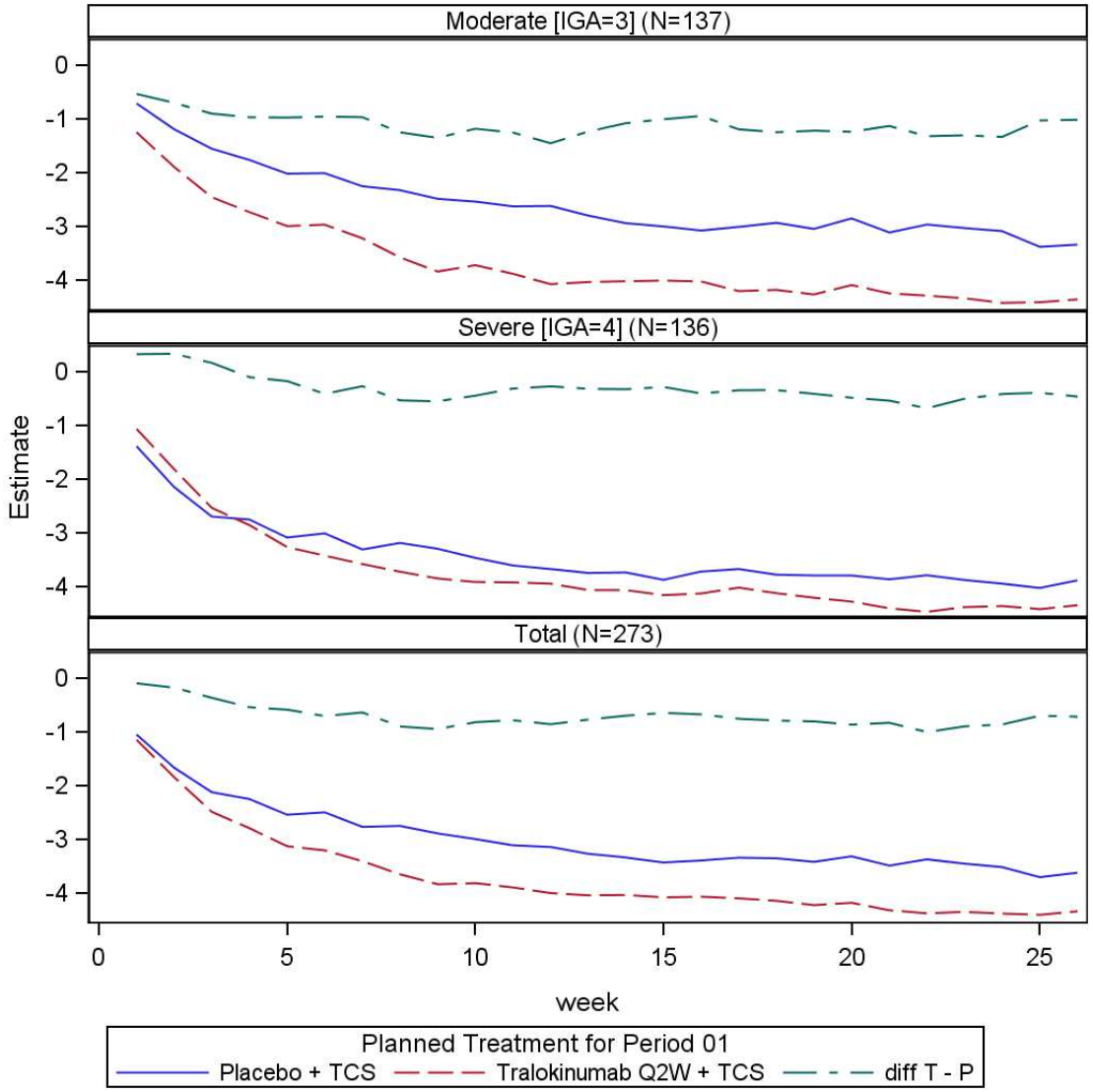
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.418.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 21 chg	55	-4.2 (2.76)	-3.87 (0.28)	61	-4.2 (2.49)	-4.41 (0.27)	-0.54 (-1.32, 0.24) [-0.21 (-0.57, 0.16)]	0.173
Week 22	57	3.1 (2.79)		60	2.2 (2.04)			
Week 22 chg	57	-4.1 (2.80)	-3.79 (0.28)	60	-4.4 (2.44)	-4.47 (0.27)	-0.68 (-1.46, 0.10) [-0.26 (-0.62, 0.10)]	0.085
Week 23	57	3.0 (2.75)		60	2.3 (2.15)			
Week 23 chg	57	-4.1 (2.66)	-3.88 (0.28)	60	-4.2 (2.60)	-4.38 (0.27)	-0.51 (-1.28, 0.27) [-0.19 (-0.56, 0.17)]	0.202
Week 24	57	3.0 (2.66)		57	2.3 (2.11)			
Week 24 chg	57	-4.2 (2.64)	-3.95 (0.28)	57	-4.3 (2.59)	-4.36 (0.28)	-0.42 (-1.20, 0.36) [-0.16 (-0.53, 0.21)]	0.292
Week 25	56	2.8 (2.65)		59	2.2 (2.06)			
Week 25 chg	56	-4.3 (2.71)	-4.03 (0.28)	59	-4.3 (2.57)	-4.42 (0.27)	-0.39 (-1.17, 0.38) [-0.15 (-0.52, 0.22)]	0.320
Week 26	53	2.9 (2.73)		61	2.3 (2.01)			
Week 26 chg	53	-4.2 (2.79)	-3.89 (0.28)	61	-4.2 (2.53)	-4.35 (0.27)	-0.46 (-1.24, 0.32) [-0.17 (-0.54, 0.19)]	0.242

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6483
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.418.4.2: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.7.420.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.24 (1.50)		138 -20.9 (16.72)	-21.09 (1.49)	-3.85 (-8.01, 0.31) 0.070 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.30 (1.51)		137 -30.8 (17.25)	-31.04 (1.50)	-4.74 (-8.92, -0.57) 0.026 [-0.27 (-0.50, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.83 (1.51)		134 -34.3 (17.49)	-34.46 (1.50)	-7.63 (-11.8, -3.43) <.001 [-0.42 (-0.66, -0.17)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.66 (1.51)		130 -36.6 (18.48)	-36.77 (1.51)	-8.11 (-12.3, -3.91) <.001 [-0.42 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.81 (1.51)		130 -38.5 (19.49)	-38.57 (1.51)	-7.76 (-12.0, -3.55) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.59 (1.52)		128 -39.5 (18.74)	-39.57 (1.52)	-7.98 (-12.2, -3.76) <.001 [-0.42 (-0.66, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3728
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.420.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 36.0 (19.61)			127 28.3 (17.87)		
Week 14 chg		126 -34.8 (20.31)	-34.25 (1.53)		127 -41.8 (20.11)	-41.39 (1.52)	-7.14 (-11.4, -2.91) <.001 [-0.35 (-0.60, -0.11)]
Week 16		124 36.3 (18.78)			123 27.0 (16.90)		
Week 16 chg		124 -34.7 (19.94)	-33.90 (1.53)		123 -43.3 (19.46)	-42.70 (1.53)	-8.80 (-13.0, -4.55) <.001 [-0.45 (-0.70, -0.19)]
Week 18		116 36.8 (19.98)			115 25.1 (15.97)		
Week 18 chg		116 -34.1 (20.70)	-33.27 (1.55)		115 -44.8 (19.27)	-43.62 (1.55)	-10.36 (-14.7, -6.05) <.001 [-0.52 (-0.78, -0.26)]
Week 20		107 35.7 (19.63)			117 25.6 (16.83)		
Week 20 chg		107 -35.6 (20.01)	-34.07 (1.57)		117 -44.9 (18.80)	-43.48 (1.54)	-9.41 (-13.7, -5.08) <.001 [-0.49 (-0.75, -0.22)]
Week 22		112 35.6 (20.27)			114 23.3 (14.77)		
Week 22 chg		112 -35.5 (20.64)	-34.08 (1.56)		114 -46.8 (19.03)	-45.23 (1.55)	-11.15 (-15.5, -6.83) <.001 [-0.56 (-0.83, -0.30)]
Week 24		112 34.6 (19.86)			117 23.3 (15.61)		
Week 24 chg		112 -36.5 (20.30)	-34.56 (1.56)		117 -46.9 (18.55)	-45.65 (1.54)	-11.09 (-15.4, -6.78) <.001 [-0.57 (-0.84, -0.31)]
Week 26		118 33.1 (18.32)			125 23.8 (16.51)		
Week 26 chg		118 -38.1 (19.21)	-36.22 (1.54)		125 -46.3 (19.60)	-45.94 (1.52)	-9.72 (-14.0, -5.46) <.001 [-0.50 (-0.76, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3728
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.420.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 64.0 (9.94)		68	68 64.0 (8.43)		
Week 2		70 50.0 (14.14)			68 41.8 (14.97)		
Week 2 chg		70 -14.0 (15.40)	-13.88 (1.89)		68 -22.2 (14.51)	-22.23 (1.92)	-8.35 (-13.7, -3.04) 0.002 [-0.56 (-0.90, -0.22)]
Week 4		69 40.4 (16.27)			68 33.3 (16.24)		
Week 4 chg		69 -23.7 (18.94)	-23.36 (1.90)		68 -30.7 (15.51)	-30.69 (1.92)	-7.33 (-12.7, -2.01) 0.007 [-0.42 (-0.76, -0.08)]
Week 6		67 40.2 (15.96)			66 31.6 (15.76)		
Week 6 chg		67 -23.9 (17.48)	-23.68 (1.91)		66 -32.2 (15.06)	-32.49 (1.93)	-8.81 (-14.2, -3.45) 0.001 [-0.54 (-0.89, -0.19)]
Week 8		67 38.7 (18.57)			62 28.5 (14.63)		
Week 8 chg		67 -24.9 (19.25)	-24.83 (1.91)		62 -34.8 (14.74)	-34.94 (1.96)	-10.11 (-15.5, -4.72) <.001 [-0.59 (-0.94, -0.23)]
Week 10		66 37.7 (19.29)			63 26.3 (14.54)		
Week 10 chg		66 -26.2 (21.18)	-25.87 (1.92)		63 -37.2 (14.64)	-37.14 (1.95)	-11.28 (-16.7, -5.88) <.001 [-0.62 (-0.97, -0.26)]
Week 12		65 36.5 (18.53)			61 24.2 (14.85)		
Week 12 chg		65 -27.7 (19.50)	-27.18 (1.93)		61 -39.1 (15.25)	-39.06 (1.97)	-11.88 (-17.3, -6.46) <.001 [-0.68 (-1.04, -0.32)]
Week 14		63 34.7 (18.66)			62 24.3 (15.09)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3728
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.420.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	63	-29.3 (19.73)	-29.31 (1.94)	62	-39.1 (15.48)	-39.02 (1.96)	-9.70 (-15.1, -4.28) <.001 [-0.55 (-0.90, -0.19)]
Week 16	61	34.7 (16.62)		59	23.1 (14.43)		
Week 16 chg	61	-29.5 (19.49)	-28.69 (1.95)	59	-40.5 (15.58)	-40.39 (1.98)	-11.70 (-17.2, -6.23) <.001 [-0.66 (-1.03, -0.29)]
Week 18	58	35.6 (19.57)		59	22.5 (12.90)		
Week 18 chg	58	-28.8 (20.95)	-27.97 (1.97)	59	-40.9 (14.57)	-40.90 (1.98)	-12.93 (-18.4, -7.43) <.001 [-0.72 (-1.09, -0.34)]
Week 20	56	33.6 (18.07)		58	21.9 (13.91)		
Week 20 chg	56	-31.3 (20.63)	-30.37 (1.99)	58	-41.8 (15.02)	-41.09 (1.99)	-10.72 (-16.2, -5.19) <.001 [-0.60 (-0.97, -0.22)]
Week 22	55	33.1 (18.60)		57	22.5 (14.87)		
Week 22 chg	55	-31.4 (20.94)	-30.55 (1.99)	57	-41.4 (16.30)	-40.79 (1.99)	-10.25 (-15.8, -4.70) <.001 [-0.55 (-0.92, -0.17)]
Week 24	53	31.4 (18.04)		58	20.7 (14.04)		
Week 24 chg	53	-32.7 (20.47)	-31.17 (2.01)	58	-43.1 (14.72)	-42.37 (1.99)	-11.21 (-16.8, -5.65) <.001 [-0.63 (-1.01, -0.25)]
Week 26	59	29.9 (16.13)		61	19.7 (14.08)		
Week 26 chg	59	-34.3 (18.62)	-33.24 (1.96)	61	-44.0 (15.34)	-43.67 (1.97)	-10.43 (-15.9, -4.96) <.001 [-0.61 (-0.98, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3728
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.420.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	67 77.9 (11.69)		70	70 76.2 (12.00)		
Week 2		67 56.9 (20.16)			70 56.6 (18.14)		
Week 2 chg		67 -21.1 (16.07)	-20.75 (2.34)		70 -19.6 (18.63)	-19.86 (2.29)	0.89 (-5.56, 7.33) 0.787 [0.05 (-0.28, 0.39)]
Week 4		65 47.5 (19.78)			69 44.9 (17.16)		
Week 4 chg		65 -30.3 (17.40)	-29.29 (2.35)		69 -31.0 (18.92)	-31.27 (2.30)	-1.99 (-8.47, 4.50) 0.546 [-0.11 (-0.45, 0.23)]
Week 6		65 46.7 (21.17)			68 39.9 (16.56)		
Week 6 chg		65 -31.1 (20.22)	-29.96 (2.35)		68 -36.2 (19.47)	-36.35 (2.30)	-6.39 (-12.9, 0.10) 0.054 [-0.32 (-0.66, 0.02)]
Week 8		66 44.5 (21.26)			68 37.8 (17.85)		
Week 8 chg		66 -33.2 (19.80)	-32.44 (2.34)		68 -38.3 (21.30)	-38.43 (2.30)	-5.99 (-12.5, 0.49) 0.070 [-0.29 (-0.63, 0.05)]
Week 10		65 40.8 (20.63)			67 36.2 (20.00)		
Week 10 chg		65 -36.9 (19.77)	-35.76 (2.35)		67 -39.8 (23.18)	-39.90 (2.31)	-4.14 (-10.6, 2.36) 0.211 [-0.19 (-0.53, 0.15)]
Week 12		63 40.8 (17.77)			67 36.2 (18.15)		
Week 12 chg		63 -37.4 (18.69)	-35.89 (2.36)		67 -39.9 (21.55)	-40.14 (2.31)	-4.25 (-10.8, 2.26) 0.200 [-0.21 (-0.56, 0.13)]
Week 14		63 37.3 (20.58)			65 32.1 (19.53)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3728
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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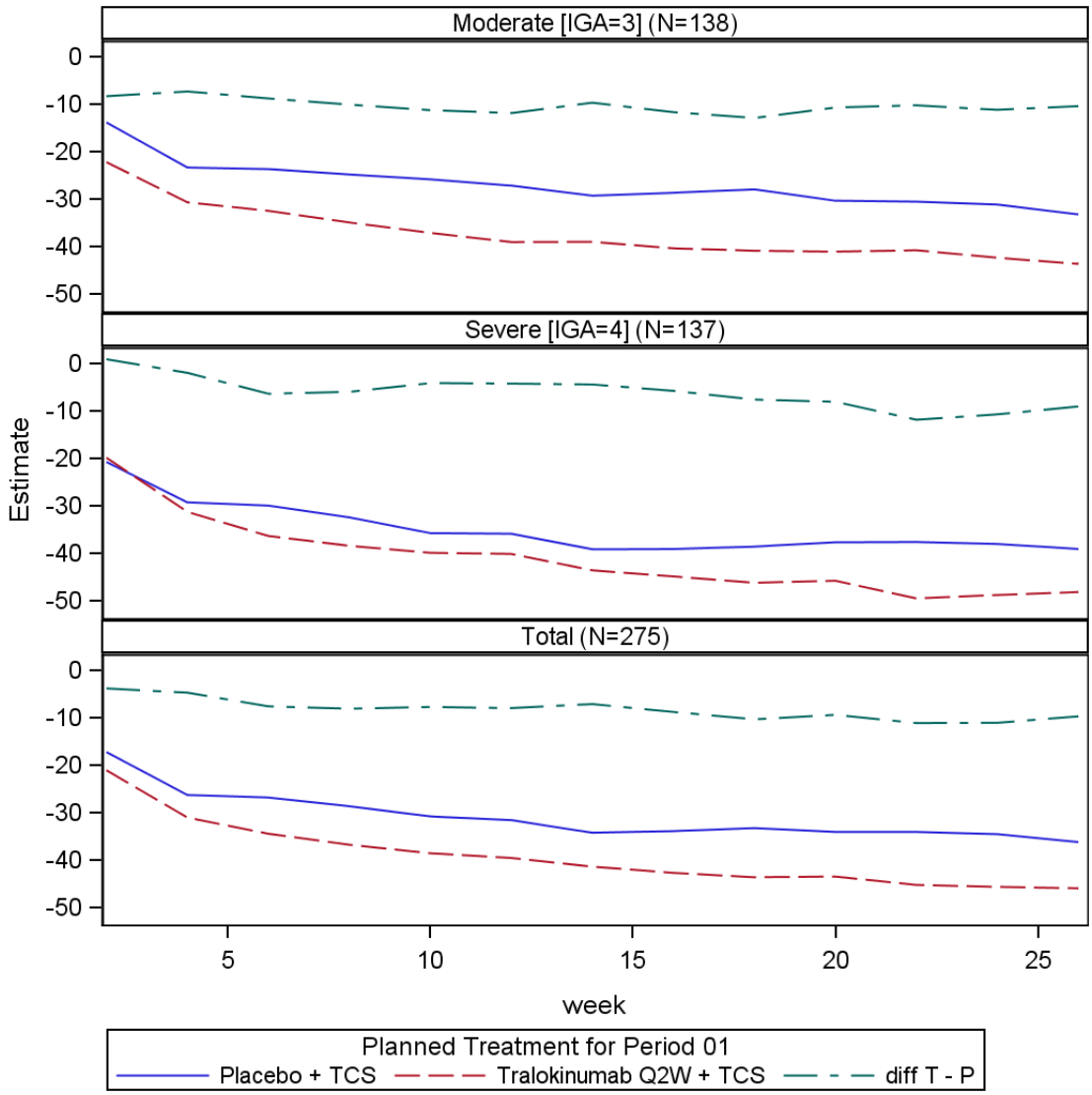
Table 1.7.420.4.1: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	63	-40.2 (19.53)	-39.16 (2.36)	65	-44.3 (23.55)	-43.60 (2.32)	-4.44 (-11.0, 2.09) 0.182 [-0.20 (-0.55, 0.14)]
Week 16	63	37.9 (20.66)		64	30.5 (18.29)		
Week 16 chg	63	-39.8 (19.17)	-39.11 (2.36)	64	-45.8 (22.27)	-44.88 (2.32)	-5.78 (-12.3, 0.76) 0.083 [-0.28 (-0.63, 0.07)]
Week 18	58	38.0 (20.49)		56	27.8 (18.39)		
Week 18 chg	58	-39.4 (19.22)	-38.59 (2.40)	56	-48.9 (22.63)	-46.22 (2.38)	-7.62 (-14.3, -0.97) 0.025 [-0.36 (-0.73, 0.01)]
Week 20	51	37.9 (21.17)		59	29.2 (18.71)		
Week 20 chg	51	-40.3 (18.35)	-37.70 (2.46)	59	-48.0 (21.58)	-45.79 (2.36)	-8.09 (-14.8, -1.38) 0.018 [-0.40 (-0.78, -0.02)]
Week 22	57	38.1 (21.65)		57	24.2 (14.74)		
Week 22 chg	57	-39.4 (19.76)	-37.64 (2.40)	57	-52.2 (20.15)	-49.50 (2.37)	-11.87 (-18.5, -5.21) <.001 [-0.59 (-0.97, -0.22)]
Week 24	59	37.6 (21.09)		59	25.8 (16.74)		
Week 24 chg	59	-39.8 (19.72)	-38.04 (2.39)	59	-50.8 (21.11)	-48.78 (2.36)	-10.74 (-17.4, -4.12) 0.002 [-0.53 (-0.89, -0.16)]
Week 26	59	36.4 (19.89)		64	27.6 (17.81)		
Week 26 chg	59	-41.9 (19.20)	-39.09 (2.39)	64	-48.5 (22.85)	-48.17 (2.32)	-9.08 (-15.7, -2.50) 0.007 [-0.43 (-0.79, -0.07)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3728
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.420.4.2: Total, Disease severity (IGA), change in SCORAD, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.7.422.4.1: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
DLQI Score										
Total										
Baseline	137	134	16.4 (6.33)		138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)			132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.13 (0.44)		132	-7.5 (5.92)	-7.54 (0.44)	-0.41 (-1.63, 0.81) [-0.07 (-0.31, 0.17)]	0.508
Week 4		130	7.8 (6.27)			135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.30 (0.44)		135	-9.0 (6.32)	-9.13 (0.44)	-0.82 (-2.04, 0.40) [-0.13 (-0.37, 0.11)]	0.185
Week 6		123	7.3 (6.07)			126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.60 (0.45)		126	-10.0 (6.75)	-9.85 (0.44)	-1.25 (-2.48, -0.01) [-0.18 (-0.43, 0.07)]	0.048
Week 8		127	6.9 (5.70)			128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.94 (0.44)		128	-10.6 (6.29)	-10.36 (0.44)	-1.41 (-2.64, -0.19) [-0.22 (-0.46, 0.03)]	0.024
Week 12		123	6.8 (5.89)			124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.29 (0.45)		124	-10.6 (5.77)	-10.55 (0.44)	-1.26 (-2.50, -0.02) [-0.19 (-0.44, 0.06)]	0.046
Week 16		120	6.5 (5.63)			118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.45)		118	-11.0 (5.99)	-11.14 (0.45)	-1.46 (-2.71, -0.22) [-0.23 (-0.49, 0.02)]	0.022

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.422.4.1: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	6.2 (5.67)		111	4.1 (3.92)			
Week 20 chg	102	-9.9 (7.06)	-9.64 (0.46)	111	-11.4 (5.58)	-11.49 (0.45)	-1.85 (-3.13, -0.57) [-0.29 (-0.56, -0.02)]	0.005
Week 26	110	6.3 (5.26)		116	4.3 (4.31)			
Week 26 chg	110	-10.4 (6.56)	-9.61 (0.46)	116	-11.1 (6.17)	-11.28 (0.45)	-1.67 (-2.93, -0.41) [-0.26 (-0.52, -0.00)]	0.010

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.422.4.1: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]										
Baseline	70	68	15.0 (6.67)		68	68	15.2 (5.87)			
Week 2		67	9.8 (6.98)			65	7.5 (5.19)			
Week 2 chg		67	-5.4 (5.91)	-5.31 (0.62)		65	-7.9 (5.19)	-7.66 (0.62)	-2.35 (-4.07, -0.63) [-0.42 (-0.77, -0.08)]	0.008
Week 4		66	8.5 (7.04)			68	6.1 (5.52)			
Week 4 chg		66	-6.6 (6.95)	-6.47 (0.62)		68	-9.1 (5.54)	-9.02 (0.61)	-2.55 (-4.27, -0.83) [-0.41 (-0.75, -0.06)]	0.004
Week 6		63	7.2 (5.93)			65	5.9 (6.24)			
Week 6 chg		63	-7.8 (6.92)	-7.59 (0.62)		65	-9.3 (6.63)	-9.09 (0.62)	-1.50 (-3.23, 0.24) [-0.22 (-0.57, 0.13)]	0.090
Week 8		62	7.0 (5.79)			62	4.9 (5.12)			
Week 8 chg		62	-7.9 (6.96)	-7.61 (0.63)		62	-10.5 (5.87)	-9.91 (0.63)	-2.30 (-4.04, -0.55) [-0.36 (-0.71, -0.00)]	0.010
Week 12		63	7.0 (6.15)			60	4.4 (3.58)			
Week 12 chg		63	-8.3 (6.79)	-8.11 (0.62)		60	-10.6 (5.05)	-10.27 (0.63)	-2.16 (-3.91, -0.41) [-0.36 (-0.72, -0.00)]	0.016
Week 16		59	6.7 (5.85)			56	4.0 (3.93)			
Week 16 chg		59	-8.2 (6.22)	-8.31 (0.63)		56	-10.6 (5.40)	-10.76 (0.64)	-2.44 (-4.22, -0.67) [-0.42 (-0.79, -0.05)]	0.007
Week 20		56	6.6 (6.58)			56	3.3 (2.62)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.422.4.1: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 20 chg	56	-8.5 (7.36)	-8.21 (0.64)	56	-11.3 (4.74)	-11.31 (0.64)	-3.10 (-4.88, -1.32) <.001 [-0.50 (-0.88, -0.12)]
Week 26	54	6.1 (5.53)		56	3.4 (3.20)		
Week 26 chg	54	-9.0 (6.43)	-8.49 (0.64)	56	-11.3 (5.41)	-11.00 (0.64)	-2.51 (-4.30, -0.72) 0.006 [-0.42 (-0.80, -0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.422.4.1: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 17.8 (5.68)		70	69 16.5 (7.10)			
Week 2		64 8.5 (5.88)			67 9.4 (6.91)			
Week 2 chg		64 -9.2 (4.84)	-9.00 (0.62)		67 -7.2 (6.57)	-7.44 (0.61)	1.56 (-0.15, 3.28) [0.27 (-0.07, 0.61)]	0.074
Week 4		64 7.0 (5.32)			67 7.4 (6.40)			
Week 4 chg		64 -10.7 (5.73)	-10.16 (0.62)		67 -9.0 (7.07)	-9.26 (0.61)	0.90 (-0.82, 2.62) [0.14 (-0.20, 0.48)]	0.306
Week 6		60 7.4 (6.27)			61 6.2 (5.32)			
Week 6 chg		60 -10.1 (7.43)	-9.59 (0.63)		61 -10.7 (6.85)	-10.68 (0.62)	-1.09 (-2.83, 0.66) [-0.15 (-0.51, 0.20)]	0.220
Week 8		65 6.8 (5.67)			66 5.9 (5.10)			
Week 8 chg		65 -10.8 (6.45)	-10.30 (0.62)		66 -10.7 (6.71)	-10.83 (0.61)	-0.53 (-2.25, 1.19) [-0.08 (-0.42, 0.26)]	0.545
Week 12		60 6.6 (5.66)			64 5.6 (4.17)			
Week 12 chg		60 -11.3 (7.48)	-10.45 (0.63)		64 -10.7 (6.41)	-10.91 (0.62)	-0.47 (-2.21, 1.27) [-0.07 (-0.42, 0.29)]	0.598
Week 16		61 6.3 (5.46)			62 4.9 (3.81)			
Week 16 chg		61 -11.6 (6.46)	-11.04 (0.63)		62 -11.3 (6.52)	-11.57 (0.62)	-0.53 (-2.27, 1.22) [-0.08 (-0.43, 0.27)]	0.552
Week 20		46 5.8 (4.35)			55 4.9 (4.77)			

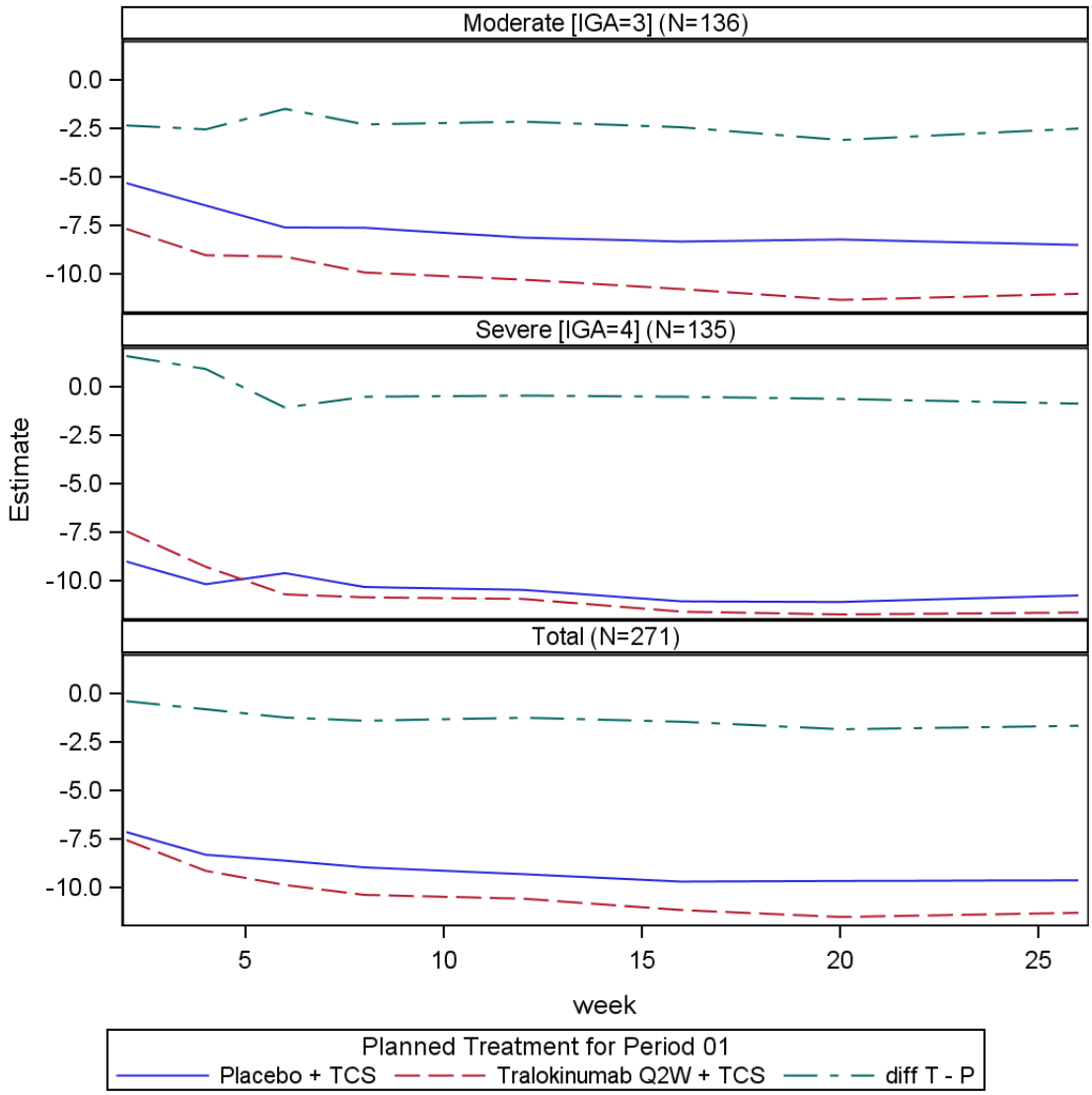
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.422.4.1: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	46	-11.7 (6.32)	-11.07 (0.67)	55	-11.5 (6.37)	-11.71 (0.63)	-0.64 (-2.46, 1.18) [-0.10 (-0.49, 0.29)]	0.490
Week 26	56	6.4 (5.04)		60	5.1 (5.05)			
Week 26 chg	56	-11.8 (6.44)	-10.73 (0.64)	60	-11.0 (6.85)	-11.61 (0.62)	-0.88 (-2.65, 0.89) [-0.13 (-0.50, 0.23)]	0.328

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.422.4.2: Total, Disease severity (IGA), change in DLQI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.7.423.4.1: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total									
Total									
Baseline	137	134	20.9 (5.72)		138	135	21.3 (5.12)		
Week 2		130	15.1 (6.91)			130	13.5 (6.31)		
Week 2 chg		130	-5.9 (6.29)	-5.97 (0.55)		130	-7.7 (5.43)	-7.67 (0.55)	-1.71 (-3.23, -0.18) 0.029 [-0.29 (-0.53, -0.05)]
Week 4		130	13.8 (7.45)			133	11.6 (6.30)		
Week 4 chg		130	-7.1 (7.56)	-7.11 (0.55)		133	-9.7 (6.02)	-9.53 (0.55)	-2.42 (-3.94, -0.89) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123	13.5 (7.81)			124	10.9 (5.95)		
Week 6 chg		123	-7.2 (8.29)	-7.29 (0.56)		124	-10.6 (6.27)	-10.35 (0.56)	-3.07 (-4.61, -1.52) <.001 [-0.42 (-0.67, -0.17)]
Week 8		127	13.1 (7.02)			126	9.9 (5.79)		
Week 8 chg		127	-7.6 (7.95)	-7.70 (0.55)		126	-11.5 (6.10)	-11.16 (0.55)	-3.46 (-5.00, -1.92) <.001 [-0.49 (-0.74, -0.24)]
Week 12		123	13.0 (7.39)			122	9.2 (5.72)		
Week 12 chg		123	-8.0 (8.26)	-7.91 (0.56)		122	-12.4 (6.20)	-11.78 (0.56)	-3.88 (-5.43, -2.33) <.001 [-0.53 (-0.79, -0.28)]
Week 16		120	13.0 (7.69)			116	9.1 (5.58)		
Week 16 chg		120	-8.0 (8.09)	-8.08 (0.56)		116	-12.2 (6.39)	-11.81 (0.56)	-3.73 (-5.30, -2.17) <.001 [-0.51 (-0.77, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0283
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.423.4.1: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	12.3 (7.64)		109	9.0 (5.60)			
Week 20 chg	102	-8.3 (7.60)	-8.25 (0.58)	109	-12.2 (6.08)	-11.90 (0.57)	-3.65 (-5.25, -2.05) [-0.53 (-0.81, -0.26)]	<.001
Week 26	110	11.8 (7.82)		114	8.2 (5.65)			
Week 26 chg	110	-8.9 (8.23)	-8.77 (0.57)	114	-12.8 (6.59)	-12.64 (0.57)	-3.86 (-5.44, -2.28) [-0.52 (-0.79, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0283
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.423.4.1: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	68 20.0 (6.11)		68	68 21.3 (4.52)			
Week 2		67 15.2 (7.49)			65 13.0 (5.99)			
Week 2 chg		67 -4.9 (6.17)	-4.99 (0.76)		65 -8.3 (5.37)	-8.15 (0.76)	-3.16 (-5.28, -1.04) [-0.55 (-0.89, -0.20)]	0.004
Week 4		66 14.0 (8.17)			68 11.0 (6.01)			
Week 4 chg		66 -6.1 (7.48)	-6.30 (0.76)		68 -10.3 (5.67)	-10.07 (0.75)	-3.77 (-5.88, -1.65) [-0.57 (-0.91, -0.22)]	<.001
Week 6		63 13.0 (8.00)			65 10.2 (5.80)			
Week 6 chg		63 -6.8 (7.90)	-7.16 (0.77)		65 -11.0 (6.23)	-10.64 (0.76)	-3.48 (-5.62, -1.34) [-0.49 (-0.84, -0.14)]	0.002
Week 8		62 12.9 (6.86)			62 8.9 (5.34)			
Week 8 chg		62 -6.8 (7.20)	-7.13 (0.77)		62 -12.3 (5.72)	-11.80 (0.77)	-4.67 (-6.83, -2.51) [-0.72 (-1.08, -0.36)]	<.001
Week 12		63 12.8 (7.48)			60 8.6 (5.92)			
Week 12 chg		63 -7.4 (7.78)	-7.63 (0.77)		60 -12.9 (6.51)	-11.98 (0.78)	-4.35 (-6.51, -2.19) [-0.60 (-0.97, -0.24)]	<.001
Week 16		59 12.7 (7.53)			56 8.8 (6.03)			
Week 16 chg		59 -7.3 (7.60)	-7.77 (0.78)		56 -12.5 (6.90)	-11.78 (0.79)	-4.01 (-6.20, -1.82) [-0.55 (-0.92, -0.18)]	<.001
Week 20		56 11.6 (7.71)			56 8.6 (4.80)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0283
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.423.4.1: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	56	-8.3 (7.34)	-8.54 (0.79)	56	-12.5 (5.95)	-11.95 (0.79)	-3.42 (-5.63, -1.21) [-0.51 (-0.89, -0.14)]	0.003
Week 26	54	10.5 (7.28)		56	7.7 (5.42)			
Week 26 chg	54	-9.0 (8.00)	-9.82 (0.80)	56	-13.7 (6.05)	-12.78 (0.79)	-2.97 (-5.20, -0.74) [-0.42 (-0.80, -0.04)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0283
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.423.4.1: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 21.8 (5.18)		70	67 21.3 (5.71)			
Week 2		63 15.0 (6.30)			65 14.0 (6.63)			
Week 2 chg		63 -7.0 (6.27)	-6.97 (0.80)		65 -7.2 (5.46)	-7.23 (0.80)	-0.26 (-2.49, 1.97) [-0.04 (-0.39, 0.30)]	0.819
Week 4		64 13.5 (6.70)			65 12.3 (6.57)			
Week 4 chg		64 -8.1 (7.55)	-7.87 (0.80)		65 -9.0 (6.35)	-9.07 (0.80)	-1.20 (-3.43, 1.03) [-0.17 (-0.52, 0.17)]	0.290
Week 6		60 14.0 (7.63)			59 11.5 (6.09)			
Week 6 chg		60 -7.5 (8.72)	-7.37 (0.81)		59 -10.3 (6.35)	-10.11 (0.81)	-2.74 (-5.01, -0.48) [-0.36 (-0.72, 0.00)]	0.018
Week 8		65 13.3 (7.22)			64 10.9 (6.09)			
Week 8 chg		65 -8.4 (8.59)	-8.16 (0.80)		64 -10.8 (6.42)	-10.59 (0.80)	-2.43 (-4.66, -0.20) [-0.32 (-0.67, 0.03)]	0.033
Week 12		60 13.2 (7.36)			62 9.8 (5.51)			
Week 12 chg		60 -8.6 (8.76)	-8.14 (0.81)		62 -11.9 (5.89)	-11.62 (0.80)	-3.48 (-5.73, -1.22) [-0.47 (-0.83, -0.11)]	0.003
Week 16		61 13.2 (7.90)			60 9.3 (5.16)			
Week 16 chg		61 -8.7 (8.56)	-8.39 (0.81)		60 -11.9 (5.92)	-11.84 (0.81)	-3.44 (-5.70, -1.19) [-0.47 (-0.83, -0.11)]	0.003
Week 20		46 13.3 (7.54)			53 9.4 (6.36)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0283
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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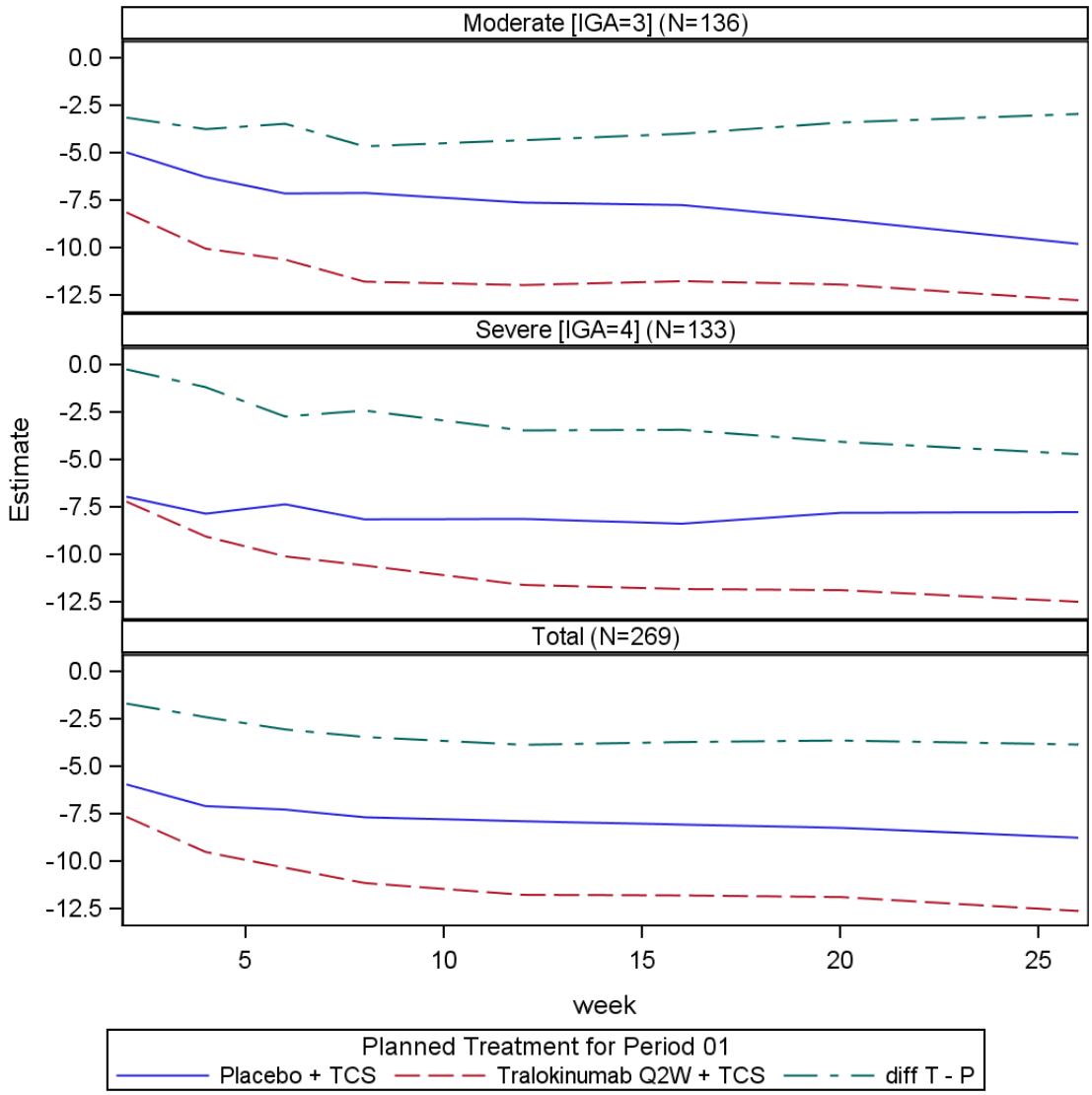
Table 1.7.423.4.1: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 20 chg	46	-8.3 (7.99)	-7.82 (0.86)	53	-12.0 (6.26)	-11.89 (0.83)	-4.07 (-6.43, -1.71) <.001 [-0.57 (-0.98, -0.17)]
Week 26	56	13.1 (8.17)		58	8.8 (5.86)		
Week 26 chg	56	-8.7 (8.52)	-7.78 (0.83)	58	-12.0 (7.01)	-12.51 (0.82)	-4.73 (-7.02, -2.44) <.001 [-0.61 (-0.98, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0283
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.7.423.4.2: Total, Disease severity (IGA), change in POEM, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.7.428.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.41 (0.22)		138 -2.8 (2.87)	-2.87 (0.22)	-0.45 (-1.08, 0.17) 0.153 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.23 (0.23)		137 -3.8 (2.99)	-3.80 (0.22)	-0.58 (-1.20, 0.05) 0.071 [-0.18 (-0.42, 0.06)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.15 (0.23)		134 -4.1 (2.81)	-4.07 (0.23)	-0.92 (-1.55, -0.29) 0.004 [-0.30 (-0.54, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.50 (0.23)		130 -4.4 (2.91)	-4.34 (0.23)	-0.84 (-1.47, -0.21) 0.009 [-0.27 (-0.51, -0.03)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.65 (0.23)		130 -4.5 (2.93)	-4.46 (0.23)	-0.81 (-1.44, -0.18) 0.012 [-0.26 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.73 (0.23)		128 -4.6 (2.96)	-4.55 (0.23)	-0.83 (-1.46, -0.19) 0.011 [-0.26 (-0.51, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4116
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.428.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	126	2.8 (2.94)		127	2.3 (2.60)			
Week 14 chg	126	-4.0 (3.48)	-3.88 (0.23)	127	-4.4 (3.07)	-4.33 (0.23)	-0.45 (-1.09, 0.18) [-0.14 (-0.38, 0.11)]	0.161
Week 16	124	2.7 (2.77)		123	1.9 (2.39)			
Week 16 chg	124	-4.1 (3.25)	-3.93 (0.23)	123	-4.7 (2.92)	-4.64 (0.23)	-0.72 (-1.36, -0.08) [-0.23 (-0.48, 0.02)]	0.027

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4116
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.7.428.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 6.4 (2.27)		68	68 6.5 (2.15)		
Week 2		70 4.6 (2.70)			68 3.5 (2.43)		
Week 2 chg		70 -1.8 (2.95)	-1.79 (0.30)		68 -3.0 (2.40)	-3.03 (0.31)	-1.24 (-2.09, -0.39) 0.004 [-0.46 (-0.80, -0.12)]
Week 4		69 3.9 (2.81)			68 2.6 (2.68)		
Week 4 chg		69 -2.5 (3.34)	-2.49 (0.30)		68 -3.9 (2.56)	-3.90 (0.31)	-1.41 (-2.26, -0.56) 0.001 [-0.47 (-0.81, -0.13)]
Week 6		67 3.7 (2.79)			66 2.4 (2.56)		
Week 6 chg		67 -2.7 (3.22)	-2.76 (0.31)		66 -4.1 (2.51)	-4.03 (0.31)	-1.26 (-2.12, -0.41) 0.004 [-0.44 (-0.78, -0.09)]
Week 8		67 3.5 (2.59)			62 1.8 (2.14)		
Week 8 chg		67 -2.9 (3.10)	-2.94 (0.31)		62 -4.7 (2.30)	-4.56 (0.31)	-1.62 (-2.48, -0.76) <.001 [-0.59 (-0.94, -0.24)]
Week 10		66 3.4 (2.76)			63 2.0 (2.44)		
Week 10 chg		66 -3.1 (3.38)	-3.13 (0.31)		63 -4.5 (2.68)	-4.39 (0.31)	-1.26 (-2.12, -0.40) 0.004 [-0.41 (-0.76, -0.06)]
Week 12		65 3.1 (2.72)			61 1.8 (2.29)		
Week 12 chg		65 -3.4 (3.30)	-3.32 (0.31)		61 -4.8 (2.70)	-4.63 (0.31)	-1.31 (-2.17, -0.44) 0.003 [-0.43 (-0.79, -0.08)]
Week 14		63 3.1 (2.96)			62 2.1 (2.52)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4116
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.428.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	63	-3.3 (3.57)	-3.32 (0.31)	62	-4.4 (2.78)	-4.31 (0.31)	-0.99 (-1.86, -0.13) [-0.31 (-0.66, 0.04)]	0.025
Week 16	61	2.8 (2.63)		59	1.7 (2.29)			
Week 16 chg	61	-3.5 (3.20)	-3.54 (0.31)	59	-4.8 (2.55)	-4.72 (0.32)	-1.19 (-2.06, -0.31) [-0.41 (-0.77, -0.05)]	0.008

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4116
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.428.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]												
Baseline	67	67	7.1 (2.09)			70	70	6.8 (2.56)				
Week 2		67	4.0 (2.78)				70	4.2 (2.93)				
Week 2 chg		67	-3.2 (2.87)	-3.04	(0.33)		70	-2.6 (3.26)	-2.71	(0.33)	0.33 (-0.59, 1.25) [0.11 (-0.23, 0.44)]	0.477
Week 4		65	2.9 (2.60)				69	3.1 (2.68)				
Week 4 chg		65	-4.2 (3.02)	-3.97	(0.33)		69	-3.6 (3.37)	-3.72	(0.33)	0.24 (-0.68, 1.17) [0.08 (-0.26, 0.41)]	0.603
Week 6		65	3.4 (3.00)				68	2.7 (2.60)				
Week 6 chg		65	-3.8 (3.33)	-3.53	(0.33)		68	-4.1 (3.09)	-4.13	(0.33)	-0.60 (-1.52, 0.33) [-0.19 (-0.53, 0.15)]	0.203
Week 8		66	2.9 (2.76)				68	2.7 (2.69)				
Week 8 chg		66	-4.3 (3.37)	-4.06	(0.33)		68	-4.1 (3.36)	-4.16	(0.33)	-0.10 (-1.03, 0.82) [-0.03 (-0.37, 0.31)]	0.825
Week 10		65	2.7 (2.79)				67	2.3 (2.67)				
Week 10 chg		65	-4.4 (3.27)	-4.17	(0.33)		67	-4.4 (3.16)	-4.53	(0.33)	-0.36 (-1.28, 0.57) [-0.11 (-0.45, 0.23)]	0.446
Week 12		63	2.7 (2.64)				67	2.4 (2.62)				
Week 12 chg		63	-4.4 (3.38)	-4.14	(0.34)		67	-4.4 (3.20)	-4.50	(0.33)	-0.36 (-1.29, 0.57) [-0.11 (-0.45, 0.23)]	0.446
Week 14		63	2.4 (2.91)				65	2.5 (2.67)				

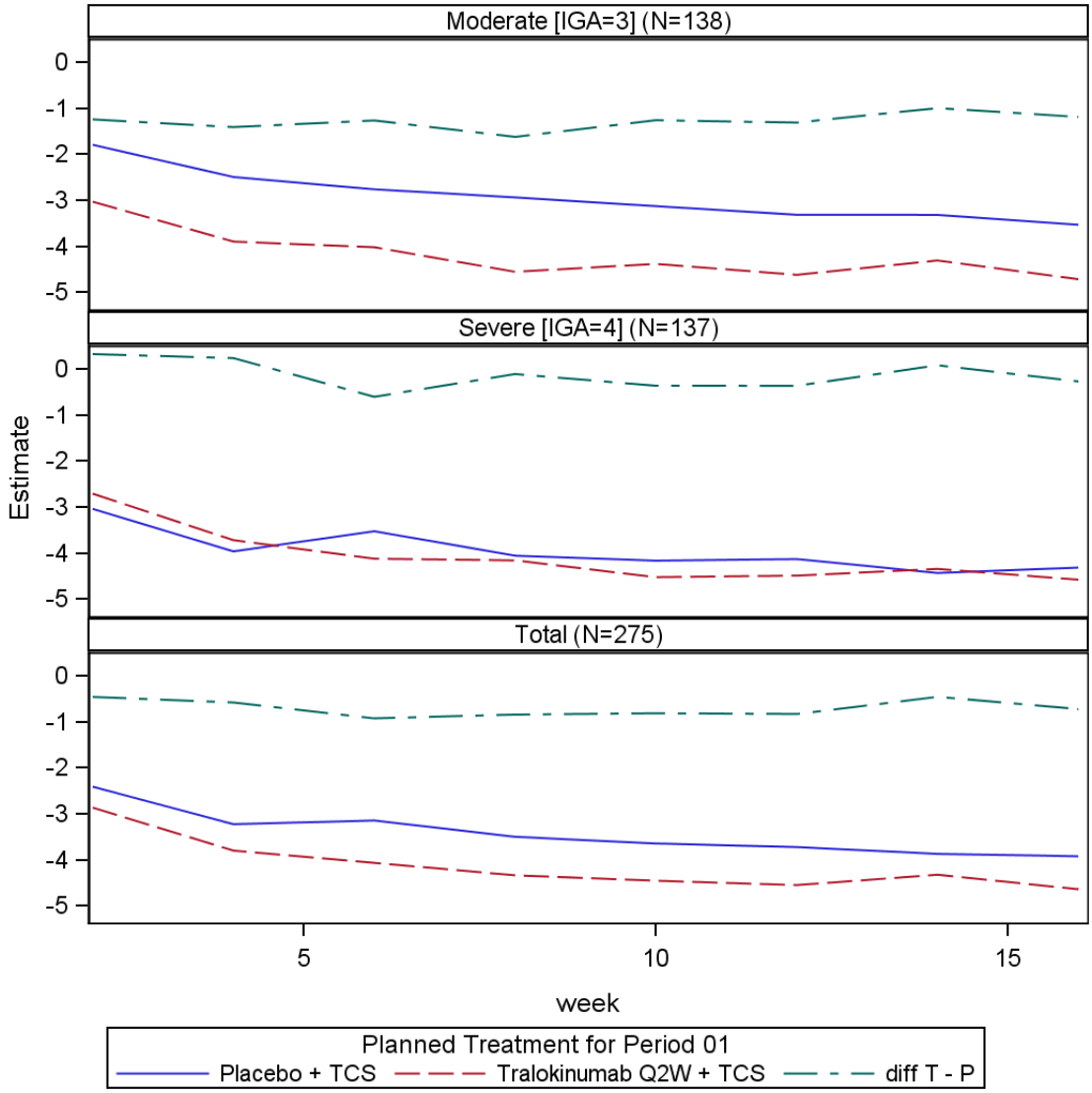
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4116
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.428.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	63	-4.7 (3.27)	-4.44 (0.34)	65	-4.3 (3.34)	-4.35 (0.33)	0.09 (-0.84, 1.02) [0.03 (-0.32, 0.37)]	0.852
Week 16	63	2.6 (2.91)		64	2.2 (2.48)			
Week 16 chg	63	-4.6 (3.25)	-4.32 (0.34)	64	-4.5 (3.25)	-4.59 (0.33)	-0.26 (-1.20, 0.67) [-0.08 (-0.43, 0.27)]	0.578

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4116
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.428.4.2: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.7.429.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.80 (1.50)		133	17.3 (19.49)	18.41 (1.49)	2.61 (-1.55, 6.77) 0.219 [0.13 (-0.12, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.37 (1.51)		126	18.4 (21.17)	19.36 (1.51)	2.99 (-1.23, 7.20) 0.165 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.37 (1.53)		122	18.7 (21.48)	19.47 (1.53)	2.11 (-2.15, 6.37) 0.332 [0.09 (-0.16, 0.35)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.72 (1.54)		116	17.7 (22.49)	19.74 (1.55)	5.02 (0.71, 9.33) 0.022 [0.20 (-0.05, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.429.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]									
Baseline	70	68	55.4 (21.46)		68	68	58.6 (17.74)		
Week 4		67	70.9 (18.33)			68	74.1 (15.69)		
Week 4 chg		67	15.8 (21.75)	14.54 (2.18)		68	15.5 (18.47)	16.29 (2.17)	1.74 (-4.33, 7.81) 0.572 [0.09 (-0.25, 0.42)]
Week 8		62	72.3 (19.91)			62	76.1 (17.18)		
Week 8 chg		62	16.4 (25.73)	14.67 (2.24)		62	17.7 (21.07)	17.71 (2.24)	3.04 (-3.20, 9.28) 0.338 [0.13 (-0.22, 0.48)]
Week 12		63	70.0 (22.36)			60	78.0 (15.44)		
Week 12 chg		63	14.6 (22.13)	13.34 (2.23)		60	18.8 (19.96)	19.20 (2.26)	5.87 (-0.40, 12.13) 0.066 [0.28 (-0.08, 0.63)]
Week 16		59	68.4 (23.65)			56	78.6 (16.72)		
Week 16 chg		59	12.3 (25.61)	11.06 (2.27)		56	18.1 (21.44)	20.04 (2.32)	8.99 (2.58, 15.39) 0.006 [0.38 (0.01, 0.75)]

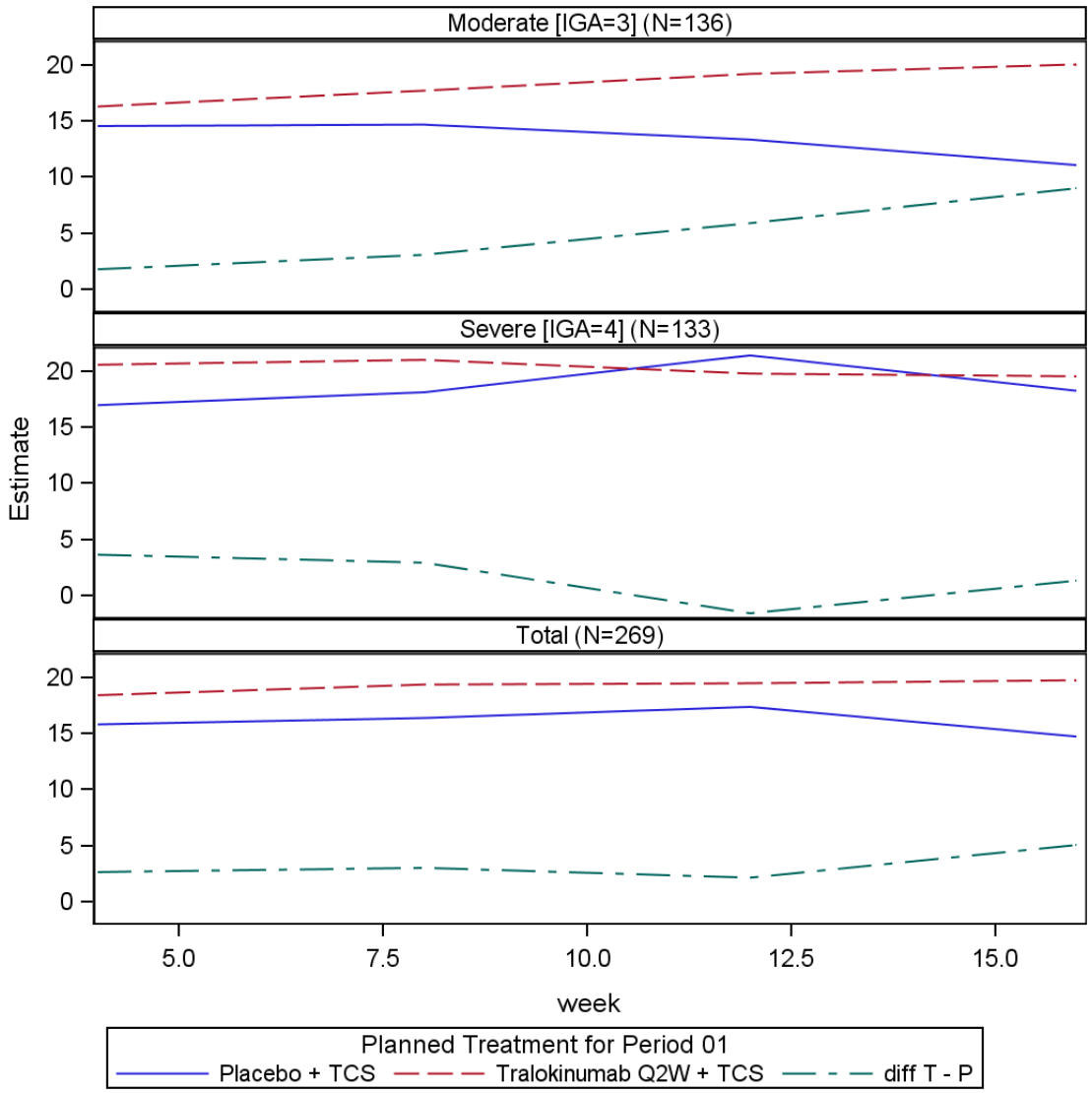
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.429.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 49.5 (22.25)		70	67 54.6 (21.83)		
Week 4		64 68.3 (16.86)			65 73.5 (17.89)		
Week 4 chg		64 18.9 (22.00)	16.97 (2.05)		65 19.1 (20.49)	20.58 (2.03)	3.61 (-2.10, 9.32) 0.215 [0.17 (-0.18, 0.52)]
Week 8		65 69.8 (17.62)			64 74.0 (15.33)		
Week 8 chg		65 20.0 (24.54)	18.12 (2.04)		64 19.2 (21.41)	21.01 (2.04)	2.89 (-2.82, 8.60) 0.320 [0.13 (-0.22, 0.47)]
Week 12		60 72.4 (15.52)			62 72.8 (16.12)		
Week 12 chg		60 23.8 (23.13)	21.41 (2.09)		62 18.7 (23.02)	19.78 (2.06)	-1.63 (-7.43, 4.17) 0.581 [-0.07 (-0.43, 0.28)]
Week 16		61 69.9 (20.07)			60 72.9 (16.95)		
Week 16 chg		61 21.0 (27.32)	18.25 (2.08)		60 17.4 (23.60)	19.54 (2.08)	1.29 (-4.53, 7.10) 0.664 [0.05 (-0.31, 0.41)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1014
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.429.4.2: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.7.430.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score											
Total											
Baseline	137	134	52.5 (21.97)			138	135	56.6 (19.90)			
Week 4		131	69.6 (17.61)				133	73.8 (16.74)			
Week 4 chg		131	17.3 (21.84)	15.83	(1.52)		133	17.3 (19.49)	18.45	(1.50)	2.62 (-1.59, 6.82) 0.222 [0.13 (-0.11, 0.37)]
Week 8		127	71.0 (18.73)				126	75.1 (16.24)			
Week 8 chg		127	18.2 (25.09)	16.39	(1.53)		126	18.4 (21.17)	19.38	(1.53)	2.99 (-1.26, 7.24) 0.168 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)				122	75.4 (15.94)			
Week 12 chg		123	19.1 (23.00)	17.49	(1.54)		122	18.7 (21.48)	19.49	(1.54)	1.99 (-2.30, 6.29) 0.362 [0.09 (-0.16, 0.34)]
Week 16		120	69.2 (21.82)				116	75.7 (17.01)			
Week 16 chg		120	16.7 (26.74)	14.83	(1.55)		116	17.7 (22.49)	19.65	(1.57)	4.82 (0.48, 9.16) 0.030 [0.19 (-0.06, 0.45)]
Week 20		103	72.7 (20.07)				108	77.3 (14.52)			
Week 20 chg		103	19.3 (25.56)	17.99	(1.61)		108	21.6 (20.57)	21.18	(1.59)	3.20 (-1.26, 7.65) 0.159 [0.14 (-0.13, 0.41)]
Week 26		113	72.4 (20.84)				116	76.4 (17.02)			
Week 26 chg		113	20.5 (25.83)	17.77	(1.58)		116	19.5 (21.18)	20.31	(1.56)	2.53 (-1.84, 6.90) 0.256 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1841
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.430.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]											
Baseline	70	68	55.4 (21.46)			68	68	58.6 (17.74)			
Week 4		67	70.9 (18.33)				68	74.1 (15.69)			
Week 4 chg		67	15.8 (21.75)	14.64	(2.20)		68	15.5 (18.47)	16.40	(2.19)	1.76 (-4.37, 7.88) 0.573 [0.09 (-0.25, 0.42)]
Week 8		62	72.3 (19.91)				62	76.1 (17.18)			
Week 8 chg		62	16.4 (25.73)	14.73	(2.25)		62	17.7 (21.07)	17.76	(2.26)	3.02 (-3.26, 9.31) 0.344 [0.13 (-0.22, 0.48)]
Week 12		63	70.0 (22.36)				60	78.0 (15.44)			
Week 12 chg		63	14.6 (22.13)	13.50	(2.24)		60	18.8 (19.96)	19.18	(2.28)	5.67 (-0.63, 11.98) 0.078 [0.27 (-0.09, 0.62)]
Week 16		59	68.4 (23.65)				56	78.6 (16.72)			
Week 16 chg		59	12.3 (25.61)	11.22	(2.28)		56	18.1 (21.44)	19.91	(2.33)	8.70 (2.26, 15.13) 0.008 [0.37 (-0.00, 0.74)]
Week 20		57	72.5 (22.04)				56	78.7 (13.86)			
Week 20 chg		57	16.8 (25.07)	15.28	(2.31)		56	20.1 (19.14)	20.62	(2.33)	5.34 (-1.11, 11.80) 0.104 [0.24 (-0.13, 0.61)]
Week 26		55	71.6 (22.64)				56	79.3 (16.21)			
Week 26 chg		55	16.6 (26.28)	14.66	(2.34)		56	21.0 (20.75)	21.17	(2.33)	6.51 (0.02, 13.01) 0.049 [0.28 (-0.10, 0.65)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1841
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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.

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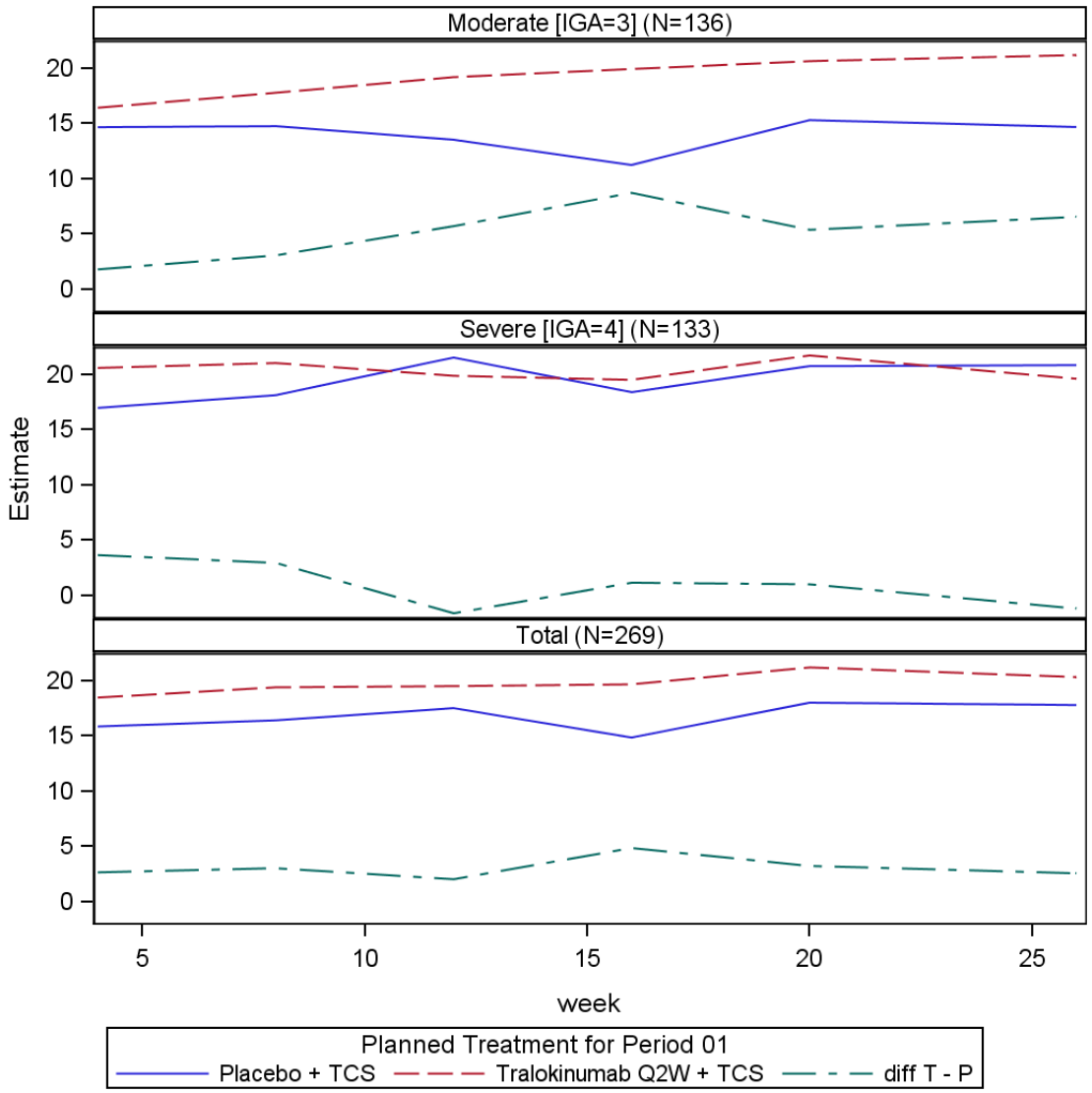
Table 1.7.430.4.1: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 49.5 (22.25)		70	67 54.6 (21.83)		
Week 4		64 68.3 (16.86)			65 73.5 (17.89)		
Week 4 chg		64 18.9 (22.00)	16.95 (2.08)		65 19.1 (20.49)	20.57 (2.06)	3.62 (-2.17, 9.41) 0.219 [0.17 (-0.18, 0.52)]
Week 8		65 69.8 (17.62)			64 74.0 (15.33)		
Week 8 chg		65 20.0 (24.54)	18.11 (2.07)		64 19.2 (21.41)	21.02 (2.07)	2.91 (-2.88, 8.70) 0.323 [0.13 (-0.22, 0.47)]
Week 12		60 72.4 (15.52)			62 72.8 (16.12)		
Week 12 chg		60 23.8 (23.13)	21.52 (2.11)		62 18.7 (23.02)	19.86 (2.08)	-1.65 (-7.52, 4.21) 0.579 [-0.07 (-0.43, 0.28)]
Week 16		61 69.9 (20.07)			60 72.9 (16.95)		
Week 16 chg		61 21.0 (27.32)	18.38 (2.10)		60 17.4 (23.60)	19.49 (2.10)	1.12 (-4.76, 7.00) 0.709 [0.04 (-0.31, 0.40)]
Week 20		46 73.0 (17.56)			52 75.8 (15.18)		
Week 20 chg		46 22.3 (26.12)	20.74 (2.23)		52 23.2 (22.08)	21.71 (2.16)	0.97 (-5.16, 7.10) 0.755 [0.04 (-0.36, 0.44)]
Week 26		58 73.2 (19.15)			60 73.6 (17.42)		
Week 26 chg		58 24.2 (25.06)	20.82 (2.12)		60 18.1 (21.65)	19.59 (2.10)	-1.23 (-7.14, 4.68) 0.683 [-0.05 (-0.41, 0.31)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1841
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.7.430.4.2: Total, Disease severity (IGA), change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.7.431.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 26		117 2.9 (2.55)			122 2.1 (2.00)		
Week 26 chg		116 -4.0 (2.53)	-3.74 (0.21)		121 -4.1 (2.47)	-4.34 (0.20)	-0.60 (-1.17, -0.03) 0.040 [-0.24 (-0.50, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5642
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.431.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 6.7 (1.60)		68	67 6.0 (2.00)		
Week 26		60 2.9 (2.31)			59 1.8 (1.90)		
Week 26 chg		60 -3.8 (2.32)	-3.56 (0.27)		58 -4.1 (2.45)	-4.35 (0.27)	-0.79 (-1.56, -0.02) 0.045 [-0.33 (-0.69, 0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5642
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.431.4.1: Total, Disease severity (IGA), change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 7.1 (1.68)		70	70 6.6 (2.18)			
Week 26		57 3.0 (2.79)			63 2.4 (2.07)			
Week 26 chg		56 -4.1 (2.75)	-3.92 (0.31)		63 -4.2 (2.51)	-4.35 (0.30)	-0.42 (-1.28, 0.44) [-0.16 (-0.52, 0.20)]	0.331

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5642
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.434.4.1: Total, Disease severity (IGA), SCORAD 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	21 (15.2)	11.7 (5.02;18.46)	4.3 (1.66;10.96)	5.0 (1.80;13.99)	0.0009	0.4171
Placebo + TCS	137	5 (3.6)					
Moderate [IGA=3]							
Tralokinumab Q2W + TCS	68	12 (17.6)	15.0 (5.34;24.74)	6.5 (1.50;27.92)	8.6 (1.68;43.88)	0.0033	
Placebo + TCS	70	2 (2.9)					
Severe [IGA=4]							
Tralokinumab Q2W + TCS	70	9 (12.9)	8.4 (-0.85;17.68)	2.9 (0.81;10.27)	3.2 (0.82;12.31)	0.0840	
Placebo + TCS	67	3 (4.5)					

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. Treatment policy estimand: Missing values at Week 26 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

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Table 1.7.437.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss								
Total								
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)			
Week 26		121 2.5 (2.71)			127 1.6 (2.07)			
Week 26 chg		121 -4.4 (3.09)	-4.30 (0.21)		127 -5.0 (2.78)	-5.09 (0.21)	-0.78 (-1.37, -0.20) [-0.27 (-0.52, -0.02)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1652
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.437.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 6.4 (2.27)		68	68 6.5 (2.15)			
Week 26		60 2.4 (2.73)			61 1.2 (1.80)			
Week 26 chg		60 -4.0 (3.11)	-4.02 (0.29)		61 -5.3 (2.30)	-5.23 (0.28)	-1.22 (-2.01, -0.42) [-0.44 (-0.80, -0.08)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1652
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.437.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	67 7.1 (2.09)		70	70 6.8 (2.56)			
Week 26		61 2.5 (2.72)			66 2.0 (2.24)			
Week 26 chg		61 -4.8 (3.04)	-4.55 (0.32)		66 -4.7 (3.15)	-4.95 (0.30)	-0.40 (-1.27, 0.48) [-0.13 (-0.48, 0.22)]	0.370

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1652
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.438.4.1: Total, Disease severity (IGA), change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 26		121 33.4 (18.31)			127 24.1 (16.65)		
Week 26 chg		121 -37.9 (19.30)	-37.26 (1.53)		127 -45.9 (19.70)	-46.62 (1.50)	-9.36 (-13.6, -5.13) <.001 [-0.48 (-0.73, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6783
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.438.4.1: Total, Disease severity (IGA), change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 64.0 (9.94)		68	68 64.0 (8.43)			
Week 26		60 29.9 (15.99)			61 19.7 (14.08)			
Week 26 chg		60 -34.4 (18.47)	-33.90 (1.86)		61 -44.0 (15.34)	-44.22 (1.85)	-10.33 (-15.5, -5.13) [-0.61 (-0.97, -0.24)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6783
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.438.4.1: Total, Disease severity (IGA), change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	67 77.9 (11.69)		70	70 76.2 (12.00)		
Week 26		61 36.8 (19.88)			66 28.1 (17.88)		
Week 26 chg		61 -41.3 (19.62)	-40.26 (2.43)		66 -47.7 (22.99)	-48.69 (2.34)	-8.43 (-15.1, -1.74) 0.014 [-0.39 (-0.74, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6783
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.439.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)							
Total							
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)		
Week 26		117 3.9 (2.53)			122 3.0 (1.94)		
Week 26 chg		116 -3.6 (2.55)	-3.47 (0.20)		121 -4.2 (2.13)	-4.31 (0.20)	-0.84 (-1.41, -0.28) 0.004 [-0.36 (-0.62, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6996
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.439.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 7.4 (1.36)		68	67 6.9 (1.39)			
Week 26		60 3.9 (2.48)			59 2.7 (2.02)			
Week 26 chg		60 -3.5 (2.57)	-3.27 (0.29)		58 -4.1 (2.22)	-4.25 (0.30)	-0.98 (-1.81, -0.15) [-0.41 (-0.77, -0.04)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6996
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.439.4.1: Total, Disease severity (IGA), change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 7.6 (1.38)		70	70 7.6 (1.45)			
Week 26		57 3.9 (2.60)			63 3.2 (1.85)			
Week 26 chg		56 -3.7 (2.55)	-3.66 (0.29)		63 -4.4 (2.04)	-4.39 (0.27)	-0.73 (-1.52, 0.06) [-0.32 (-0.68, 0.04)]	0.070

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6996
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.440.4.1: Total, Disease severity (IGA), change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total									
Total									
Baseline	137	134	20.9 (5.72)		138	135	21.3 (5.12)		
Week 26		115	11.9 (7.89)			119	8.4 (5.90)		
Week 26 chg		113	-8.7 (8.23)	-8.90 (0.62)		116	-12.7 (6.64)	-12.63 (0.62)	-3.73 (-5.46, -2.00) <.001 [-0.50 (-0.76, -0.24)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7361
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.440.4.1: Total, Disease severity (IGA), change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	68 20.0 (6.11)		68	68 21.3 (4.52)			
Week 26		56 10.3 (7.26)			56 7.7 (5.42)			
Week 26 chg		55 -9.0 (7.92)	-9.61 (0.84)		56 -13.7 (6.05)	-13.07 (0.83)	-3.46 (-5.82, -1.11) [-0.49 (-0.87, -0.11)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7361
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.440.4.1: Total, Disease severity (IGA), change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 21.8 (5.18)		70	67 21.3 (5.71)			
Week 26		59 13.5 (8.20)			63 9.1 (6.27)			
Week 26 chg		58 -8.4 (8.57)	-8.14 (0.93)		60 -11.8 (7.07)	-12.10 (0.92)	-3.96 (-6.55, -1.37) [-0.50 (-0.87, -0.14)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7361
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.442.4.1: Total, Disease severity (IGA), change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 26		115 6.2 (5.20)			119 4.4 (4.42)		
Week 26 chg		113 -10.3 (6.57)	-10.01 (0.42)		118 -11.2 (6.17)	-11.51 (0.41)	-1.50 (-2.66, -0.34) 0.011 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1310
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.442.4.1: Total, Disease severity (IGA), change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	68 15.0 (6.67)		68	68 15.2 (5.87)			
Week 26		56 5.9 (5.49)			56 3.4 (3.20)			
Week 26 chg		55 -8.9 (6.39)	-8.85 (0.56)		56 -11.3 (5.41)	-11.33 (0.55)	-2.48 (-4.03, -0.93) [-0.42 (-0.80, -0.04)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1310
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.442.4.1: Total, Disease severity (IGA), change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 17.8 (5.68)		70	69 16.5 (7.10)		
Week 26		59 6.4 (4.95)			63 5.2 (5.16)		
Week 26 chg		58 -11.7 (6.51)	-11.03 (0.62)		62 -11.1 (6.83)	-11.66 (0.60)	-0.63 (-2.35, 1.09) 0.469 [-0.09 (-0.45, 0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1310
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.443.4.1: Total, Disease severity (IGA), change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score									
Total									
Baseline	137	137	33.8 (13.46)		138	138	32.1 (11.53)		
Week 26		121	9.0 (10.05)			127	5.8 (7.95)		
Week 26 chg		121	-25.4 (13.63)	-24.33 (0.78)		127	-26.3 (12.87)	-27.34 (0.76)	-3.02 (-5.16, -0.87) 0.006 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9906
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.443.4.1: Total, Disease severity (IGA), change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 27.1 (7.27)		68	68 26.0 (5.96)			
Week 26		60 6.5 (7.84)			61 3.3 (4.40)			
Week 26 chg		60 -21.0 (11.75)	-20.02 (0.79)		61 -22.6 (7.33)	-23.47 (0.78)	-3.45 (-5.66, -1.23) [-0.35 (-0.71, 0.01)]	0.003

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9906
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.443.4.1: Total, Disease severity (IGA), change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	67 40.9 (14.81)		70	70 38.0 (12.58)		
Week 26		61 11.5 (11.37)			66 8.0 (9.69)		
Week 26 chg		61 -29.6 (14.09)	-28.24 (1.31)		66 -29.7 (15.70)	-31.02 (1.26)	-2.78 (-6.39, 0.83) 0.129 [-0.19 (-0.54, 0.16)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9906
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.444.3.1: Total, Disease severity (IGA), change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	126	126 30.4 (12.78)		252	252 28.8 (11.97)		
Week 16		123 14.1 (14.89)			241 8.1 (9.15)		
Week 16 chg		123 -16.0 (14.04)	-15.43 (0.94)		241 -20.7 (12.33)	-20.93 (0.67)	-5.50 (-7.79, -3.22) <.001 [-0.43 (-0.64, -0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0001
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.444.3.1: Total, Disease severity (IGA), change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	66	66 22.9 (6.78)		136	136 22.9 (7.81)		
Week 16		66 8.4 (8.82)			130 6.8 (8.31)		
Week 16 chg		66 -14.6 (8.69)	-14.48 (0.96)		130 -15.9 (8.80)	-15.94 (0.69)	-1.46 (-3.79, 0.88) 0.220 [-0.17 (-0.46, 0.13)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0001
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.444.3.1: Total, Disease severity (IGA), change in EASI, ANCOVA sensitivity, LP0162-1339, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	60	60 38.7 (12.78)		116	116 35.8 (12.23)			
Week 16		57 20.7 (17.60)			111 9.5 (9.87)			
Week 16 chg		57 -17.7 (18.34)	-16.49 (1.66)		111 -26.2 (13.52)	-26.81 (1.19)	-10.32 (-14.4, -6.28) [-0.67 (-1.00, -0.35)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0001
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. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline to EOT is analysed in a linear effects model including treatment, region and strata as fixed effects and baseline value as covariate.

Table 1.7.445.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss										
Total										
Baseline	137	137	6.7 (2.21)		138	138	6.7 (2.36)			
Week 2		137	4.3 (2.75)			138	3.8 (2.71)			
Week 2 chg		137	-2.4 (2.99)	-2.39 (0.22)		138	-2.8 (2.87)	-2.85 (0.22)	-0.46 (-1.07, 0.15) [-0.16 (-0.39, 0.08)]	0.140
Week 4		134	3.4 (2.75)			137	2.9 (2.68)			
Week 4 chg		134	-3.3 (3.29)	-3.20 (0.22)		137	-3.8 (2.99)	-3.79 (0.22)	-0.58 (-1.20, 0.03) [-0.19 (-0.42, 0.05)]	0.062
Week 6		132	3.5 (2.88)			134	2.6 (2.58)			
Week 6 chg		132	-3.2 (3.30)	-3.13 (0.22)		134	-4.1 (2.81)	-4.06 (0.22)	-0.93 (-1.54, -0.31) [-0.30 (-0.54, -0.06)]	0.003
Week 8		133	3.2 (2.69)			130	2.3 (2.47)			
Week 8 chg		133	-3.6 (3.29)	-3.47 (0.22)		130	-4.4 (2.91)	-4.33 (0.22)	-0.85 (-1.47, -0.24) [-0.27 (-0.52, -0.03)]	0.007
Week 10		131	3.0 (2.78)			130	2.2 (2.56)			
Week 10 chg		131	-3.8 (3.38)	-3.62 (0.22)		130	-4.5 (2.93)	-4.44 (0.22)	-0.82 (-1.43, -0.20) [-0.26 (-0.50, -0.01)]	0.009
Week 12		128	2.9 (2.68)			128	2.1 (2.48)			
Week 12 chg		128	-3.9 (3.37)	-3.70 (0.22)		128	-4.6 (2.96)	-4.53 (0.22)	-0.83 (-1.45, -0.21) [-0.26 (-0.51, -0.02)]	0.008

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0660
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.445.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	126	2.8 (2.94)		127	2.3 (2.60)			
Week 14 chg	126	-4.0 (3.48)	-3.86 (0.22)	127	-4.4 (3.07)	-4.31 (0.22)	-0.45 (-1.07, 0.17) [-0.14 (-0.38, 0.11)]	0.156
Week 16	124	2.7 (2.77)		123	1.9 (2.39)			
Week 16 chg	124	-4.1 (3.25)	-3.91 (0.22)	123	-4.7 (2.92)	-4.63 (0.22)	-0.72 (-1.34, -0.10) [-0.23 (-0.48, 0.02)]	0.024
Week 18	116	2.9 (2.83)		115	1.7 (2.27)			
Week 18 chg	116	-3.9 (3.35)	-3.71 (0.23)	115	-4.8 (2.93)	-4.81 (0.23)	-1.10 (-1.73, -0.47) [-0.35 (-0.61, -0.09)]	<.001
Week 20	107	2.6 (2.71)		117	1.8 (2.37)			
Week 20 chg	107	-4.1 (3.17)	-3.95 (0.23)	117	-4.8 (2.97)	-4.78 (0.23)	-0.83 (-1.46, -0.20) [-0.27 (-0.53, -0.01)]	0.010
Week 22	112	2.5 (2.71)		114	1.5 (2.00)			
Week 22 chg	112	-4.2 (3.34)	-4.07 (0.23)	114	-5.0 (2.85)	-4.94 (0.23)	-0.87 (-1.51, -0.24) [-0.28 (-0.54, -0.02)]	0.007
Week 24	112	2.3 (2.55)		117	1.5 (2.05)			
Week 24 chg	112	-4.4 (3.18)	-4.21 (0.23)	117	-5.1 (2.80)	-4.96 (0.23)	-0.76 (-1.39, -0.12) [-0.25 (-0.51, 0.01)]	0.019
Week 26	118	2.4 (2.70)		125	1.6 (2.07)			
Week 26 chg	118	-4.4 (3.11)	-4.20 (0.23)	125	-5.0 (2.80)	-4.92 (0.22)	-0.72 (-1.35, -0.10) [-0.24 (-0.50, 0.01)]	0.024

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0660
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.445.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	70 6.4 (2.27)		68	68 6.5 (2.15)		
Week 2		70 4.6 (2.70)			68 3.5 (2.43)		
Week 2 chg		70 -1.8 (2.95)	-1.78 (0.29)		68 -3.0 (2.40)	-3.02 (0.30)	-1.24 (-2.07, -0.42) 0.003 [-0.46 (-0.80, -0.12)]
Week 4		69 3.9 (2.81)			68 2.6 (2.68)		
Week 4 chg		69 -2.5 (3.34)	-2.48 (0.29)		68 -3.9 (2.56)	-3.89 (0.30)	-1.41 (-2.24, -0.58) <.001 [-0.47 (-0.81, -0.13)]
Week 6		67 3.7 (2.79)			66 2.4 (2.56)		
Week 6 chg		67 -2.7 (3.22)	-2.75 (0.30)		66 -4.1 (2.51)	-4.01 (0.30)	-1.26 (-2.09, -0.43) 0.003 [-0.44 (-0.78, -0.09)]
Week 8		67 3.5 (2.59)			62 1.8 (2.14)		
Week 8 chg		67 -2.9 (3.10)	-2.91 (0.30)		62 -4.7 (2.30)	-4.55 (0.30)	-1.64 (-2.47, -0.80) <.001 [-0.60 (-0.95, -0.24)]
Week 10		66 3.4 (2.76)			63 2.0 (2.44)		
Week 10 chg		66 -3.1 (3.38)	-3.10 (0.30)		63 -4.5 (2.68)	-4.38 (0.30)	-1.27 (-2.11, -0.44) 0.003 [-0.42 (-0.77, -0.07)]
Week 12		65 3.1 (2.72)			61 1.8 (2.29)		
Week 12 chg		65 -3.4 (3.30)	-3.30 (0.30)		61 -4.8 (2.70)	-4.61 (0.30)	-1.30 (-2.14, -0.46) 0.002 [-0.43 (-0.78, -0.08)]
Week 14		63 3.1 (2.96)			62 2.1 (2.52)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0660
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.445.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	63	-3.3 (3.57)	-3.33 (0.30)	62	-4.4 (2.78)	-4.29 (0.30)	-0.96 (-1.80, -0.12) [-0.30 (-0.65, 0.05)]	0.025
Week 16	61	2.8 (2.63)		59	1.7 (2.29)			
Week 16 chg	61	-3.5 (3.20)	-3.52 (0.30)	59	-4.8 (2.55)	-4.70 (0.31)	-1.18 (-2.02, -0.33) [-0.41 (-0.77, -0.04)]	0.007
Week 18	58	3.2 (2.86)		59	1.6 (2.28)			
Week 18 chg	58	-3.3 (3.50)	-3.22 (0.31)	59	-4.9 (2.56)	-4.77 (0.31)	-1.55 (-2.40, -0.70) [-0.51 (-0.87, -0.14)]	<.001
Week 20	56	2.8 (2.68)		58	1.5 (2.13)			
Week 20 chg	56	-3.7 (3.21)	-3.65 (0.31)	58	-4.9 (2.30)	-4.78 (0.31)	-1.13 (-1.98, -0.27) [-0.41 (-0.78, -0.03)]	0.010
Week 22	55	2.5 (2.54)		57	1.5 (2.03)			
Week 22 chg	55	-3.8 (3.41)	-3.90 (0.31)	57	-5.0 (2.34)	-4.87 (0.31)	-0.97 (-1.83, -0.11) [-0.33 (-0.71, 0.04)]	0.027
Week 24	53	2.1 (2.20)		58	1.2 (1.83)			
Week 24 chg	53	-4.1 (2.97)	-4.17 (0.31)	58	-5.2 (2.30)	-5.01 (0.31)	-0.84 (-1.70, 0.02) [-0.32 (-0.69, 0.06)]	0.056
Week 26	59	2.4 (2.75)		61	1.2 (1.80)			
Week 26 chg	59	-4.0 (3.12)	-3.98 (0.30)	61	-5.3 (2.30)	-5.08 (0.30)	-1.10 (-1.95, -0.26) [-0.40 (-0.77, -0.04)]	0.011

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0660
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.445.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	67 7.1 (2.09)		70	70 6.8 (2.56)			
Week 2		67 4.0 (2.78)			70 4.2 (2.93)			
Week 2 chg		67 -3.2 (2.87)	-3.02 (0.33)		70 -2.6 (3.26)	-2.69 (0.32)	0.33 (-0.58, 1.23) [0.11 (-0.23, 0.44)]	0.474
Week 4		65 2.9 (2.60)			69 3.1 (2.68)			
Week 4 chg		65 -4.2 (3.02)	-3.94 (0.33)		69 -3.6 (3.37)	-3.70 (0.32)	0.24 (-0.67, 1.15) [0.07 (-0.27, 0.41)]	0.609
Week 6		65 3.4 (3.00)			68 2.7 (2.60)			
Week 6 chg		65 -3.8 (3.33)	-3.50 (0.33)		68 -4.1 (3.09)	-4.11 (0.32)	-0.61 (-1.52, 0.30) [-0.19 (-0.53, 0.15)]	0.188
Week 8		66 2.9 (2.76)			68 2.7 (2.69)			
Week 8 chg		66 -4.3 (3.37)	-4.03 (0.33)		68 -4.1 (3.36)	-4.14 (0.32)	-0.11 (-1.02, 0.80) [-0.03 (-0.37, 0.31)]	0.807
Week 10		65 2.7 (2.79)			67 2.3 (2.67)			
Week 10 chg		65 -4.4 (3.27)	-4.14 (0.33)		67 -4.4 (3.16)	-4.49 (0.32)	-0.35 (-1.26, 0.56) [-0.11 (-0.45, 0.23)]	0.449
Week 12		63 2.7 (2.64)			67 2.4 (2.62)			
Week 12 chg		63 -4.4 (3.38)	-4.10 (0.33)		67 -4.4 (3.20)	-4.47 (0.32)	-0.37 (-1.28, 0.54) [-0.11 (-0.46, 0.23)]	0.425
Week 14		63 2.4 (2.91)			65 2.5 (2.67)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0660
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

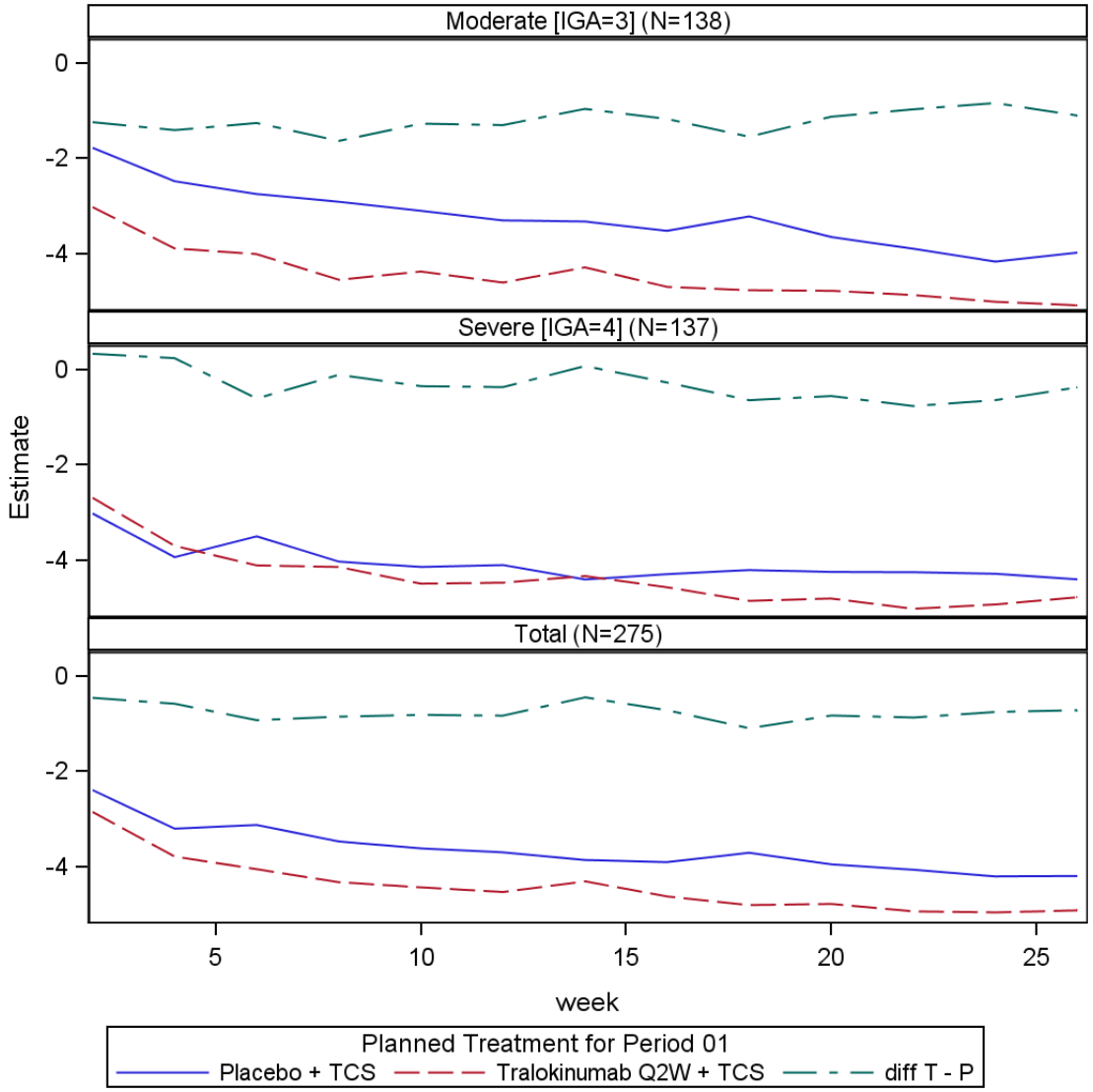
Table 1.7.445.4.1: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	63	63	-4.7 (3.27)	-4.41	(0.33)	65	65	-4.3 (3.34)	-4.33	(0.32)	0.07 (-0.84, 0.99) [0.02 (-0.32, 0.37)]	0.878
Week 16	63	63	2.6 (2.91)			64	64	2.2 (2.48)				
Week 16 chg	63	63	-4.6 (3.25)	-4.30	(0.33)	64	64	-4.5 (3.25)	-4.57	(0.33)	-0.27 (-1.19, 0.64) [-0.08 (-0.43, 0.26)]	0.556
Week 18	58	58	2.7 (2.80)			56	56	1.8 (2.28)				
Week 18 chg	58	58	-4.4 (3.12)	-4.21	(0.34)	56	56	-4.8 (3.29)	-4.85	(0.33)	-0.65 (-1.58, 0.29) [-0.20 (-0.57, 0.17)]	0.175
Week 20	51	51	2.4 (2.75)			59	59	2.0 (2.59)				
Week 20 chg	51	51	-4.6 (3.09)	-4.25	(0.34)	59	59	-4.7 (3.53)	-4.81	(0.33)	-0.56 (-1.50, 0.38) [-0.17 (-0.54, 0.21)]	0.243
Week 22	57	57	2.4 (2.88)			57	57	1.5 (1.99)				
Week 22 chg	57	57	-4.6 (3.26)	-4.25	(0.34)	57	57	-5.0 (3.30)	-5.02	(0.33)	-0.77 (-1.70, 0.17) [-0.23 (-0.60, 0.13)]	0.107
Week 24	59	59	2.4 (2.84)			59	59	1.8 (2.22)				
Week 24 chg	59	59	-4.7 (3.35)	-4.29	(0.34)	59	59	-4.9 (3.23)	-4.93	(0.33)	-0.64 (-1.57, 0.28) [-0.20 (-0.56, 0.17)]	0.173
Week 26	59	59	2.4 (2.67)			64	64	2.0 (2.25)				
Week 26 chg	59	59	-4.9 (3.06)	-4.40	(0.34)	64	64	-4.7 (3.20)	-4.78	(0.33)	-0.37 (-1.30, 0.55) [-0.12 (-0.47, 0.23)]	0.424

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0660
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

12MAY21 16:13 LP0162-Payer /p_mmrm3/t_t_igag_g45_46_w26.txt

Figure 1.7.445.4.2: Total, Disease severity (IGA), change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.446.4.1: Total, Disease severity (IGA), change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.89 (0.84)		123 -25.9 (12.78)	-26.75 (0.84)	-3.86 (-6.21, -1.51) 0.001 [-0.28 (-0.53, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5330
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.446.4.1: Total, Disease severity (IGA), change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]								
Baseline	70	70 27.1 (7.27)		68	68 26.0 (5.96)			
Week 16		61 9.0 (9.13)			59 4.3 (5.71)			
Week 16 chg		61 -18.1 (12.07)	-17.55 (0.96)		59 -21.8 (7.75)	-22.36 (0.98)	-4.81 (-7.53, -2.10) [-0.47 (-0.84, -0.11)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5330
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.446.4.1: Total, Disease severity (IGA), change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	67 40.9 (14.81)		70	70 38.0 (12.58)		
Week 16		63 12.0 (13.18)			64 8.4 (8.64)		
Week 16 chg		63 -29.2 (15.48)	-27.89 (1.36)		64 -29.6 (15.20)	-30.88 (1.35)	-3.00 (-6.81, 0.82) 0.123 [-0.20 (-0.54, 0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5330
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.463.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Physical component summary												
Total												
Baseline	137	134	44.5 (8.19)			138	134	44.5 (7.83)				
Week 8		129	50.3 (7.06)				129	51.7 (7.07)				
Week 8 chg		129	5.6 (7.75)	5.69	(0.56)		129	7.4 (7.27)	7.16	(0.56)	1.47 (-0.08, 3.03) [0.20 (-0.05, 0.44)]	0.063
Week 16		119	50.9 (7.78)				113	52.9 (6.85)				
Week 16 chg		119	6.8 (8.15)	6.49	(0.57)		113	8.0 (7.67)	7.87	(0.58)	1.39 (-0.22, 2.99) [0.17 (-0.08, 0.43)]	0.090

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9140
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.463.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]										
Baseline	70	68	45.7 (8.07)		68	68	45.3 (8.22)			
Week 8		64	50.3 (7.57)			66	51.8 (6.83)			
Week 8 chg		64	4.2 (7.06)	4.50 (0.80)		66	6.5 (7.64)	6.06 (0.79)	1.55 (-0.68, 3.78) [0.21 (-0.13, 0.56)]	0.171
Week 16		59	51.5 (7.86)			55	53.2 (7.21)			
Week 16 chg		59	5.9 (7.73)	5.48 (0.82)		55	7.2 (7.89)	7.08 (0.83)	1.61 (-0.69, 3.91) [0.21 (-0.16, 0.57)]	0.169

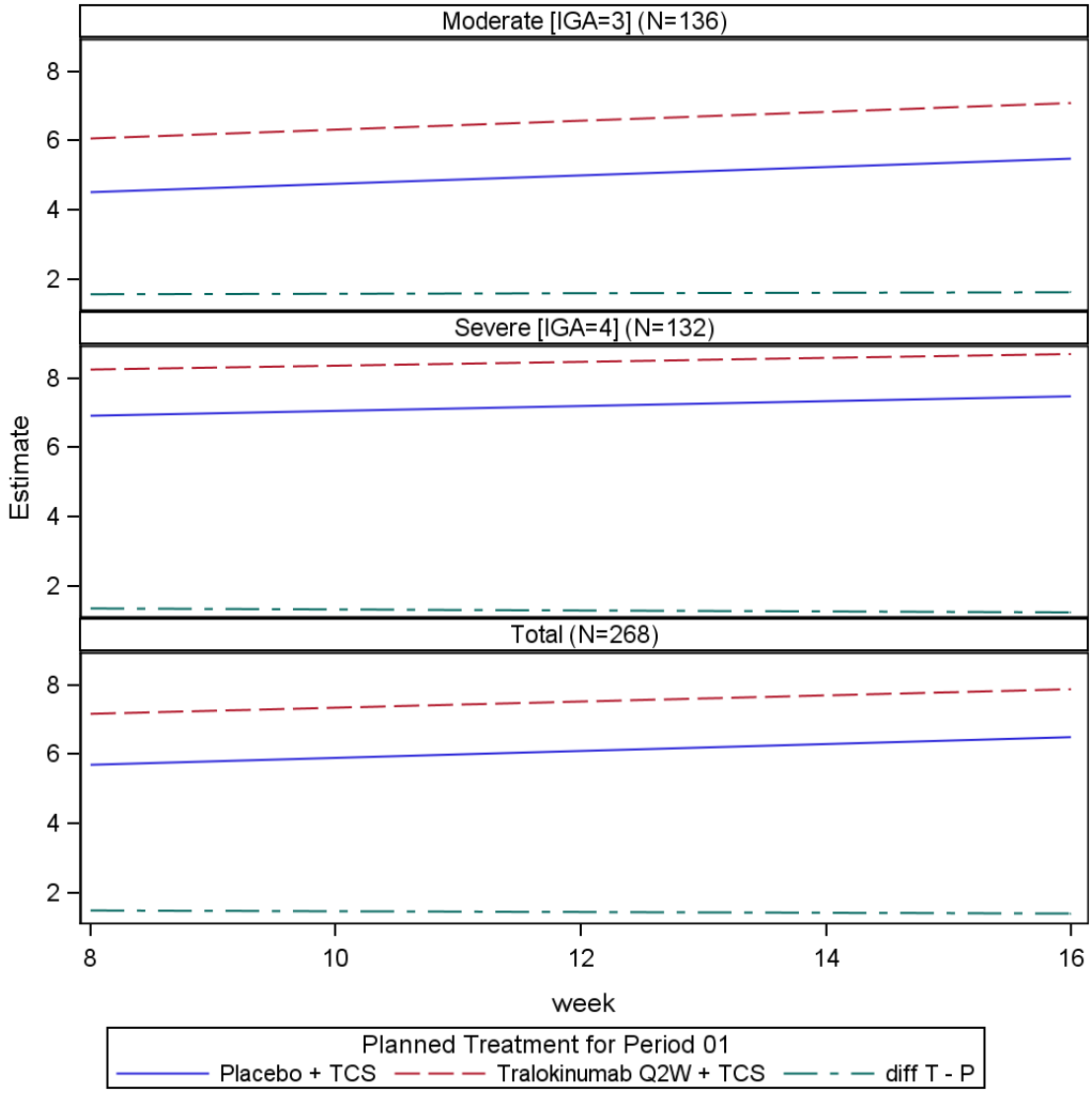
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9140
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.463.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]												
Baseline	67	66	43.2 (8.18)			70	66	43.8 (7.40)				
Week 8		65	50.3 (6.58)				63	51.7 (7.37)				
Week 8 chg		65	6.9 (8.21)	6.91	(0.78)		63	8.2 (6.82)	8.25	(0.78)	1.34 (-0.84, 3.52) [0.18 (-0.17, 0.52)]	0.228
Week 16		60	50.3 (7.73)				58	52.5 (6.53)				
Week 16 chg		60	7.8 (8.51)	7.47	(0.80)		58	8.7 (7.45)	8.70	(0.81)	1.22 (-1.02, 3.46) [0.15 (-0.21, 0.51)]	0.283

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9140
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.463.4.2: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, 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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.464.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary							
Total							
Baseline	137	134 44.9 (11.42)		138	134 46.3 (9.74)		
Week 8		129 49.6 (10.25)			129 49.7 (9.51)		
Week 8 chg		129 4.4 (7.37)	4.13 (0.64)		129 3.7 (8.69)	3.69 (0.63)	-0.44 (-2.21, 1.33) 0.625 [-0.05 (-0.30, 0.19)]
Week 16		119 49.5 (10.11)			113 49.9 (9.68)		
Week 16 chg		119 4.4 (8.65)	4.08 (0.65)		113 3.4 (8.59)	3.59 (0.66)	-0.50 (-2.32, 1.33) 0.594 [-0.06 (-0.32, 0.20)]
Week 26		110 50.4 (9.75)			112 51.4 (7.72)		
Week 26 chg		110 5.5 (8.68)	4.92 (0.67)		112 4.6 (8.26)	4.50 (0.66)	-0.42 (-2.27, 1.44) 0.660 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3183
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.464.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]										
Baseline	70	68	46.4 (11.25)		68	68	46.3 (9.19)			
Week 8		64	49.9 (10.76)			66	49.3 (9.47)			
Week 8 chg		64	3.3 (6.26)	3.20 (0.88)		66	3.4 (8.89)	3.27 (0.87)	0.07 (-2.37, 2.51) [0.01 (-0.33, 0.35)]	0.954
Week 16		59	49.2 (10.91)			55	51.1 (8.51)			
Week 16 chg		59	2.8 (7.94)	2.75 (0.90)		55	4.0 (7.42)	4.09 (0.92)	1.34 (-1.20, 3.89) [0.17 (-0.19, 0.54)]	0.300
Week 26		54	50.0 (11.15)			55	51.1 (8.02)			
Week 26 chg		54	3.6 (8.33)	3.55 (0.93)		55	4.1 (7.83)	3.78 (0.92)	0.23 (-2.35, 2.81) [0.03 (-0.35, 0.40)]	0.861

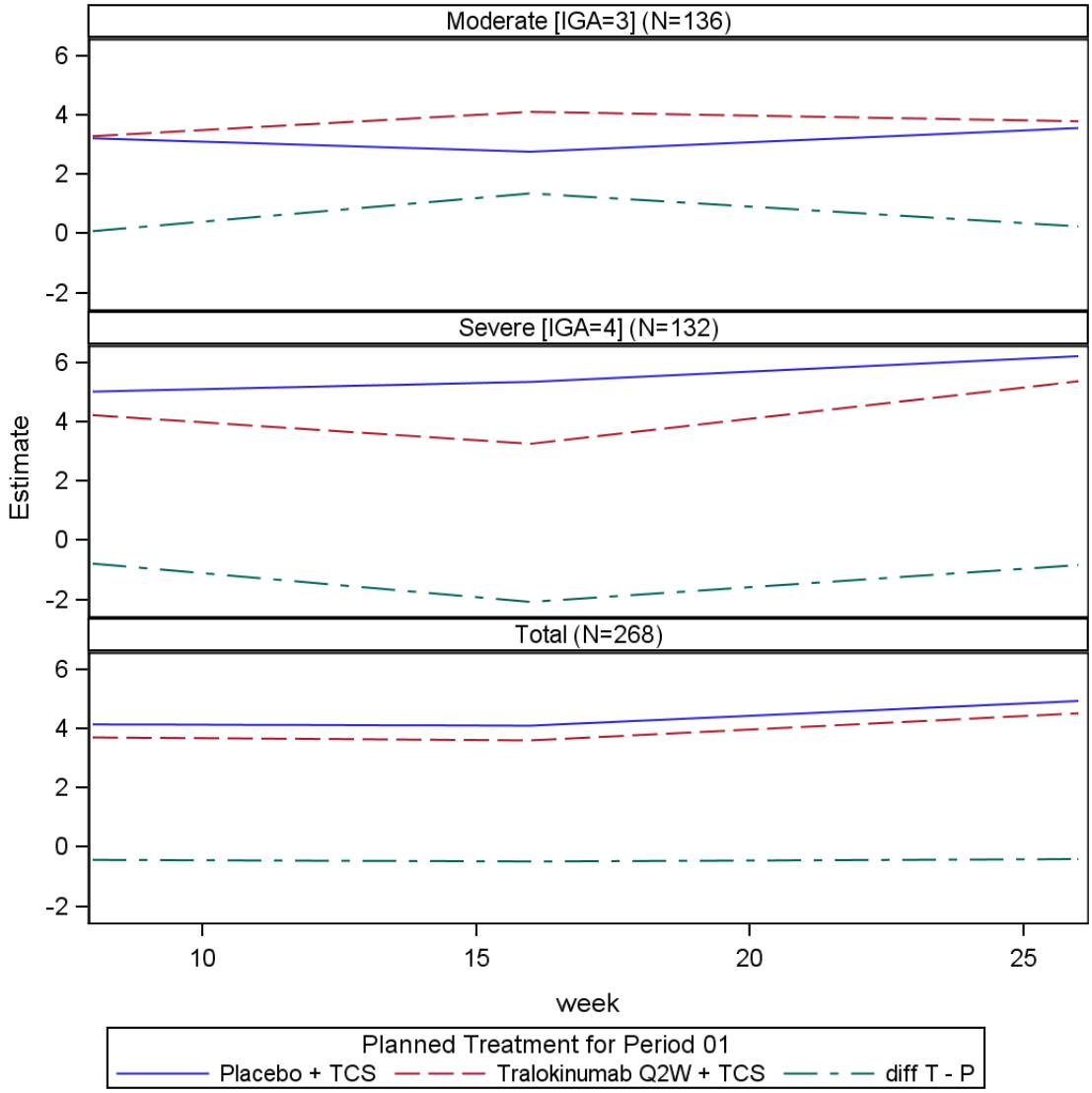
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3183
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.464.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]										
Baseline	67	66	43.4 (11.48)		70	66	46.3 (10.35)			
Week 8		65	49.3 (9.79)			63	50.0 (9.61)			
Week 8 chg		65	5.5 (8.22)	5.01 (0.91)		63	3.9 (8.54)	4.21 (0.92)	-0.80 (-3.35, 1.76) [-0.09 (-0.44, 0.25)]	0.540
Week 16		60	49.7 (9.34)			58	48.8 (10.64)			
Week 16 chg		60	5.9 (9.08)	5.33 (0.93)		58	2.9 (9.61)	3.25 (0.94)	-2.09 (-4.70, 0.53) [-0.22 (-0.59, 0.14)]	0.117
Week 26		56	50.8 (8.26)			57	51.6 (7.48)			
Week 26 chg		56	7.2 (8.70)	6.20 (0.95)		57	5.0 (8.70)	5.35 (0.95)	-0.85 (-3.50, 1.81) [-0.10 (-0.47, 0.27)]	0.531

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3183
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.464.4.2: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.465.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Physical component summary												
Total												
Baseline	137	134	44.5 (8.19)			138	134	44.5 (7.83)				
Week 8		129	50.3 (7.06)				129	51.7 (7.07)				
Week 8 chg		129	5.6 (7.75)	5.70	(0.56)		129	7.4 (7.27)	7.18	(0.56)	1.48 (-0.09, 3.04)	0.064
											[0.20 (-0.05, 0.44)]	
Week 16		119	50.9 (7.78)				113	52.9 (6.85)				
Week 16 chg		119	6.8 (8.15)	6.57	(0.57)		113	8.0 (7.67)	7.95	(0.58)	1.37 (-0.23, 2.98)	0.093
											[0.17 (-0.08, 0.43)]	
Week 26		110	50.7 (7.62)				112	52.9 (7.40)				
Week 26 chg		110	6.9 (8.19)	6.11	(0.59)		112	8.2 (7.71)	8.22	(0.58)	2.11 (0.48, 3.74)	0.011
											[0.27 (0.00, 0.53)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7987
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.465.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]										
Baseline	70	68	45.7 (8.07)		68	68	45.3 (8.22)			
Week 8		64	50.3 (7.57)			66	51.8 (6.83)			
Week 8 chg		64	4.2 (7.06)	4.53 (0.79)		66	6.5 (7.64)	6.14 (0.79)	1.62 (-0.59, 3.82) [0.22 (-0.13, 0.56)]	0.150
Week 16		59	51.5 (7.86)			55	53.2 (7.21)			
Week 16 chg		59	5.9 (7.73)	5.70 (0.81)		55	7.2 (7.89)	7.12 (0.83)	1.42 (-0.86, 3.70) [0.18 (-0.19, 0.55)]	0.222
Week 26		54	50.4 (7.74)			55	53.8 (7.26)			
Week 26 chg		54	5.4 (7.65)	5.01 (0.83)		55	8.3 (8.22)	7.87 (0.83)	2.86 (0.55, 5.17) [0.36 (-0.02, 0.74)]	0.015

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7987
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.465.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]									
Baseline	67	66	43.2 (8.18)		70	66	43.8 (7.40)		
Week 8		65	50.3 (6.58)			63	51.7 (7.37)		
Week 8 chg		65	6.9 (8.21)	6.89 (0.79)		63	8.2 (6.82)	8.21 (0.80)	1.32 (-0.90, 3.55) 0.242 [0.18 (-0.17, 0.52)]
Week 16		60	50.3 (7.73)			58	52.5 (6.53)		
Week 16 chg		60	7.8 (8.51)	7.44 (0.81)		58	8.7 (7.45)	8.77 (0.82)	1.33 (-0.94, 3.61) 0.250 [0.17 (-0.20, 0.53)]
Week 26		56	51.1 (7.56)			57	52.0 (7.51)		
Week 26 chg		56	8.2 (8.52)	7.21 (0.83)		57	8.2 (7.26)	8.57 (0.82)	1.36 (-0.94, 3.66) 0.246 [0.17 (-0.20, 0.54)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7987
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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.

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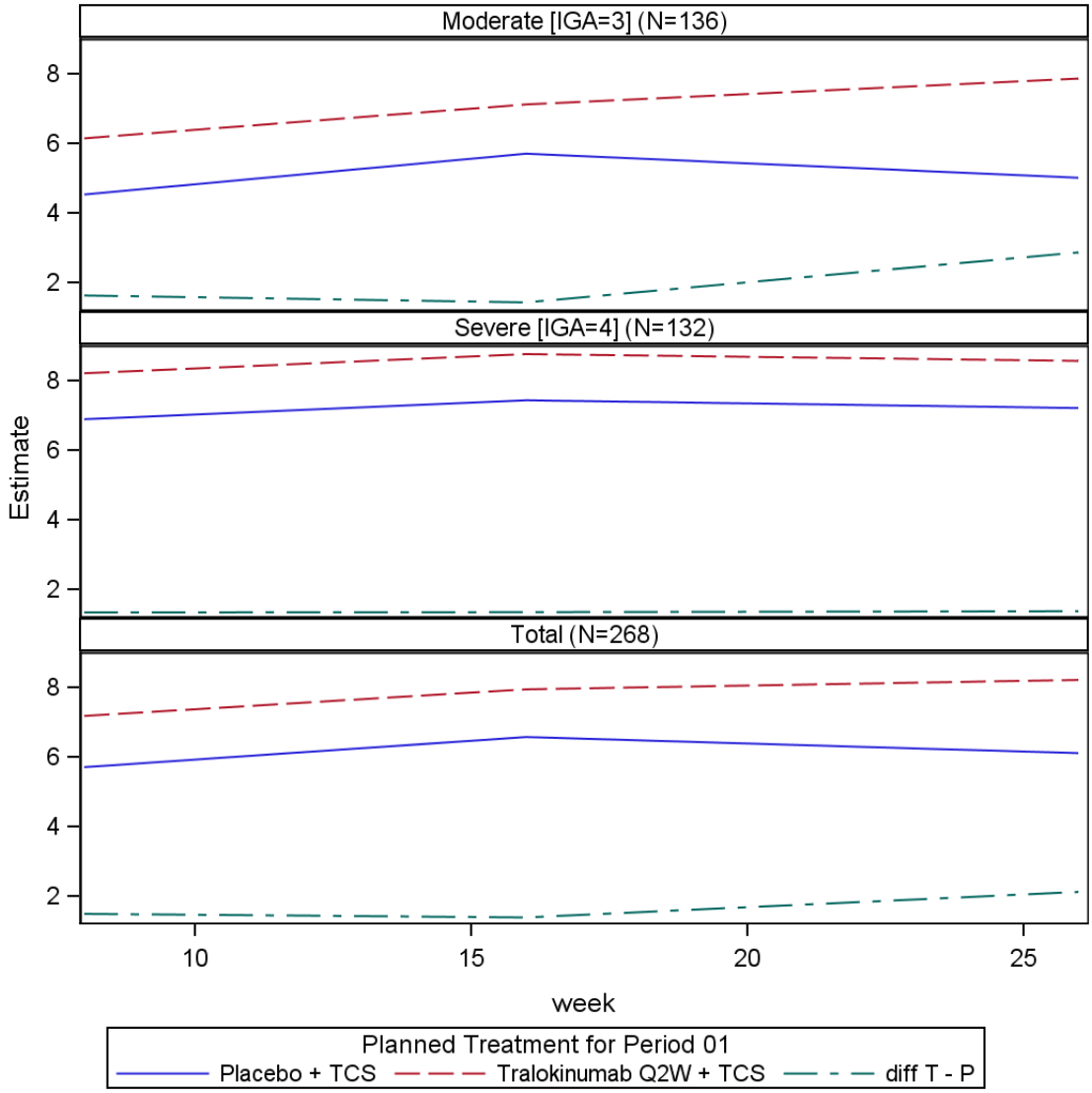
Figure 1.7.465.4.2: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.466.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary							
Total							
Baseline	137	134 44.9 (11.42)		138	134 46.3 (9.74)		
Week 8		129 49.6 (10.25)			129 49.7 (9.51)		
Week 8 chg		129 4.4 (7.37)	4.14 (0.65)		129 3.7 (8.69)	3.66 (0.65)	-0.47 (-2.28, 1.34) 0.607 [-0.06 (-0.30, 0.19)]
Week 16		119 49.5 (10.11)			113 49.9 (9.68)		
Week 16 chg		119 4.4 (8.65)	4.09 (0.67)		113 3.4 (8.59)	3.63 (0.68)	-0.46 (-2.34, 1.42) 0.629 [-0.05 (-0.31, 0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2544
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.466.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]												
Baseline	70	68	46.4 (11.25)			68	68	46.3 (9.19)				
Week 8		64	49.9 (10.76)				66	49.3 (9.47)				
Week 8 chg		64	3.3 (6.26)	3.20	(0.88)		66	3.4 (8.89)	3.26	(0.87)	0.06 (-2.37, 2.49) [0.01 (-0.34, 0.35)]	0.960
Week 16		59	49.2 (10.91)				55	51.1 (8.51)				
Week 16 chg		59	2.8 (7.94)	2.74	(0.90)		55	4.0 (7.42)	4.07	(0.93)	1.32 (-1.23, 3.88) [0.17 (-0.20, 0.54)]	0.308

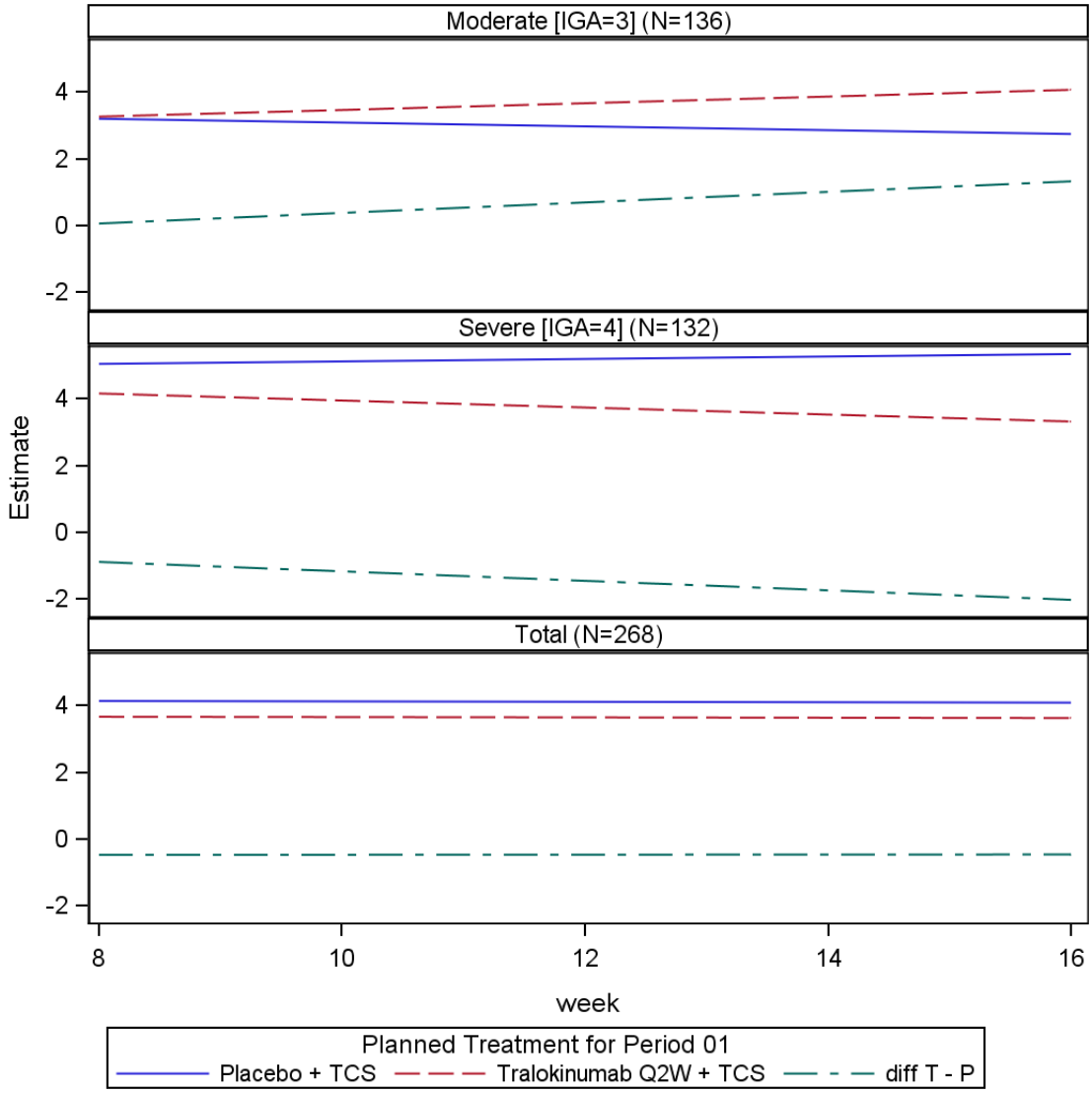
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2544
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.466.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]										
Baseline	67	66	43.4 (11.48)		70	66	46.3 (10.35)			
Week 8		65	49.3 (9.79)			63	50.0 (9.61)			
Week 8 chg		65	5.5 (8.22)	5.05 (0.96)		63	3.9 (8.54)	4.16 (0.97)	-0.89 (-3.58, 1.81) [-0.11 (-0.45, 0.24)]	0.517
Week 16		60	49.7 (9.34)			58	48.8 (10.64)			
Week 16 chg		60	5.9 (9.08)	5.34 (0.98)		58	2.9 (9.61)	3.32 (0.99)	-2.02 (-4.78, 0.74) [-0.22 (-0.58, 0.15)]	0.150

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2544
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.466.4.2: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, 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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.7.467.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary									
Total									
Baseline	137	134	44.9 (11.42)		138	134	46.3 (9.74)		
Week 8		129	49.6 (10.25)			129	49.7 (9.51)		
Week 8 chg		129	4.4 (7.37)	4.13 (0.63)		129	3.7 (8.69)	3.70 (0.63)	-0.43 (-2.18, 1.32) 0.627 [-0.05 (-0.30, 0.19)]
Week 16		119	49.5 (10.11)			113	49.9 (9.68)		
Week 16 chg		119	4.4 (8.65)	4.08 (0.68)		113	3.4 (8.59)	3.58 (0.69)	-0.50 (-2.42, 1.42) 0.611 [-0.06 (-0.32, 0.20)]
Week 26		110	50.4 (9.75)			112	51.4 (7.72)		
Week 26 chg		110	5.5 (8.68)	4.93 (0.64)		112	4.6 (8.26)	4.53 (0.64)	-0.40 (-2.18, 1.38) 0.661 [-0.05 (-0.31, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3695
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.467.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	68 46.4 (11.25)		68	68 46.3 (9.19)		
Week 8		64 49.9 (10.76)			66 49.3 (9.47)		
Week 8 chg		64 3.3 (6.26)	3.23 (0.88)		66 3.4 (8.89)	3.27 (0.87)	0.04 (-2.41, 2.50) 0.974 [0.01 (-0.34, 0.35)]
Week 16		59 49.2 (10.91)			55 51.1 (8.51)		
Week 16 chg		59 2.8 (7.94)	2.75 (0.88)		55 4.0 (7.42)	4.11 (0.90)	1.36 (-1.14, 3.86) 0.283 [0.18 (-0.19, 0.54)]
Week 26		54 50.0 (11.15)			55 51.1 (8.02)		
Week 26 chg		54 3.6 (8.33)	3.53 (0.96)		55 4.1 (7.83)	3.73 (0.95)	0.19 (-2.47, 2.86) 0.886 [0.02 (-0.35, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3695
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

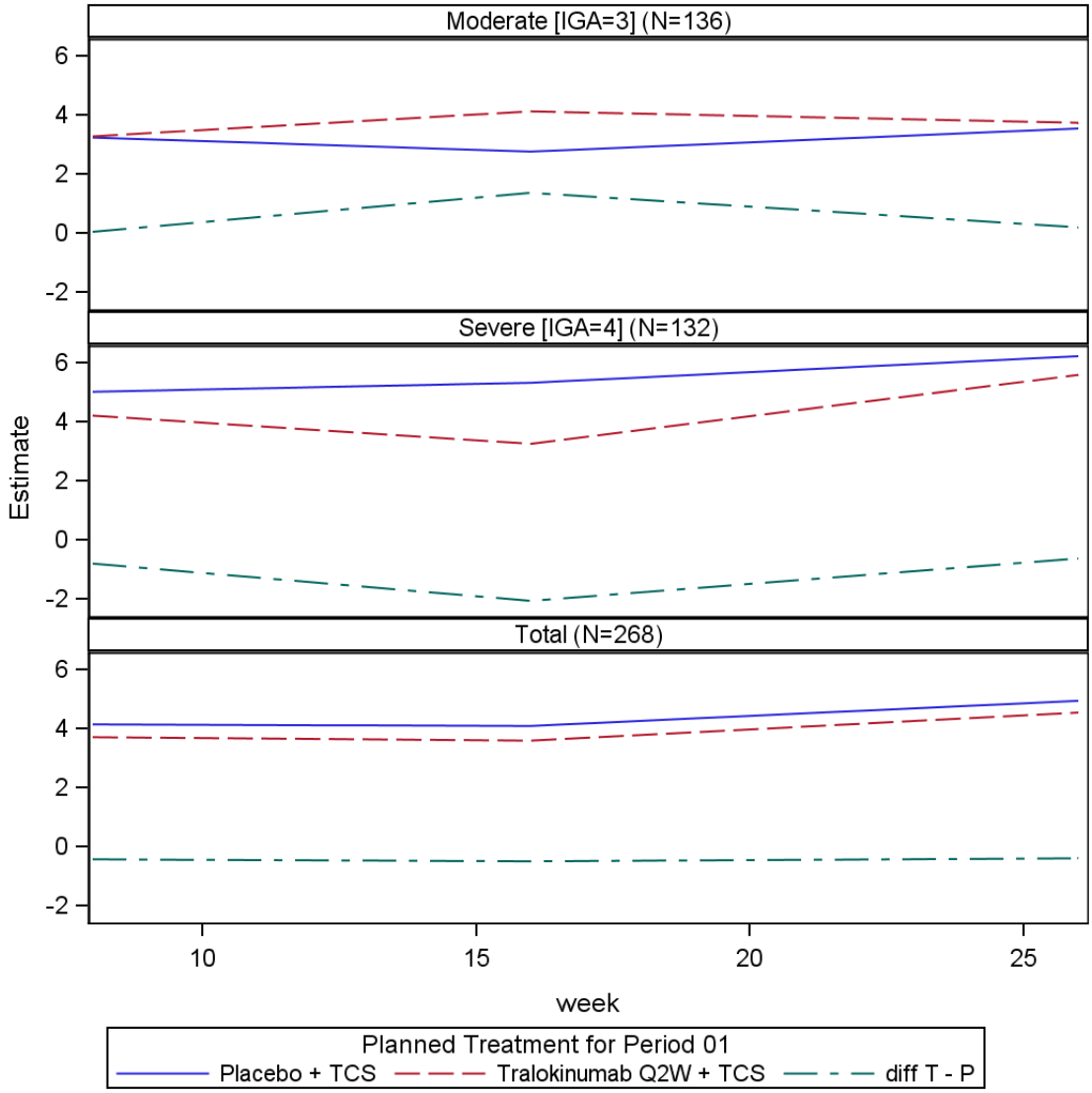
12MAY21 15:18 LP0162-Payer /p_mmrm3/t_t_igag_g67_46_w26.txt

Table 1.7.467.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]										
Baseline	67	66	43.4 (11.48)		70	66	46.3 (10.35)			
Week 8		65	49.3 (9.79)			63	50.0 (9.61)			
Week 8 chg		65	5.5 (8.22)	5.00 (0.90)		63	3.9 (8.54)	4.20 (0.91)	-0.81 (-3.35, 1.74) [-0.10 (-0.44, 0.25)]	0.532
Week 16		60	49.7 (9.34)			58	48.8 (10.64)			
Week 16 chg		60	5.9 (9.08)	5.31 (1.02)		58	2.9 (9.61)	3.25 (1.03)	-2.06 (-4.96, 0.83) [-0.22 (-0.58, 0.14)]	0.161
Week 26		56	50.8 (8.26)			57	51.6 (7.48)			
Week 26 chg		56	7.2 (8.70)	6.21 (0.85)		57	5.0 (8.70)	5.58 (0.84)	-0.63 (-3.01, 1.74) [-0.07 (-0.44, 0.30)]	0.599

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3695
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.7.467.4.2: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.468.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary									
Total									
Baseline	137	134	44.5 (8.19)		138	134	44.5 (7.83)		
Week 8		129	50.3 (7.06)			129	51.7 (7.07)		
Week 8 chg		129	5.6 (7.75)	5.70 (0.54)		129	7.4 (7.27)	7.19 (0.54)	1.49 (-0.03, 3.00) 0.054 [0.20 (-0.05, 0.44)]
Week 16		119	50.9 (7.78)			113	52.9 (6.85)		
Week 16 chg		119	6.8 (8.15)	6.57 (0.58)		113	8.0 (7.67)	7.94 (0.59)	1.37 (-0.26, 2.99) 0.100 [0.17 (-0.09, 0.43)]
Week 26		110	50.7 (7.62)			112	52.9 (7.40)		
Week 26 chg		110	6.9 (8.19)	6.09 (0.60)		112	8.2 (7.71)	8.21 (0.60)	2.13 (0.46, 3.80) 0.013 [0.27 (0.00, 0.53)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8234
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.468.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Moderate [IGA=3]										
Baseline	70	68	45.7 (8.07)		68	68	45.3 (8.22)			
Week 8		64	50.3 (7.57)			66	51.8 (6.83)			
Week 8 chg		64	4.2 (7.06)	4.55 (0.79)		66	6.5 (7.64)	6.14 (0.78)	1.59 (-0.62, 3.79) [0.22 (-0.13, 0.56)]	0.156
Week 16		59	51.5 (7.86)			55	53.2 (7.21)			
Week 16 chg		59	5.9 (7.73)	5.66 (0.83)		55	7.2 (7.89)	7.10 (0.84)	1.44 (-0.89, 3.77) [0.18 (-0.18, 0.55)]	0.223
Week 26		54	50.4 (7.74)			55	53.8 (7.26)			
Week 26 chg		54	5.4 (7.65)	5.01 (0.83)		55	8.3 (8.22)	7.88 (0.82)	2.88 (0.57, 5.18) [0.36 (-0.02, 0.74)]	0.015

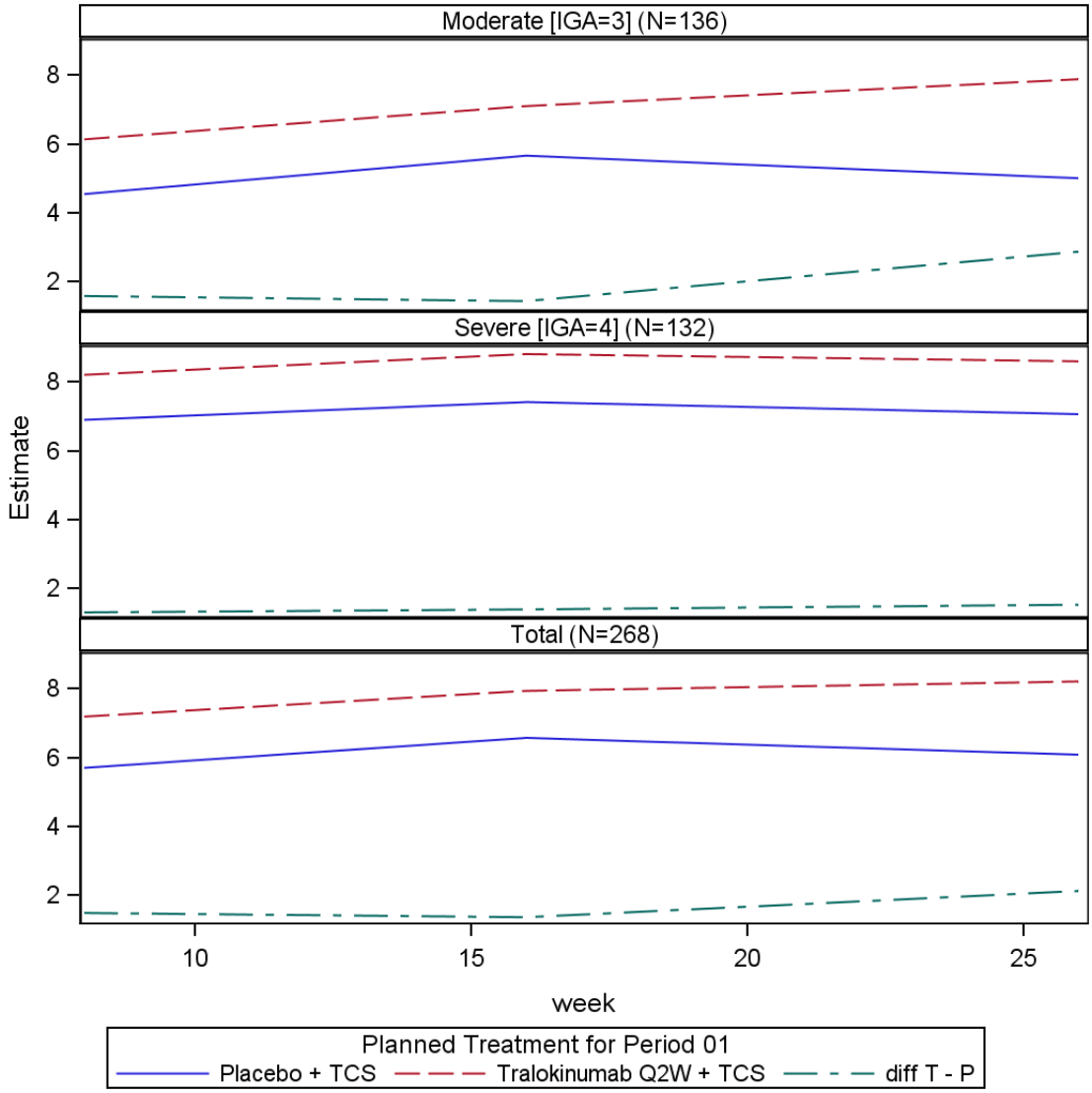
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8234
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.468.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]									
Baseline	67	66	43.2 (8.18)		70	66	43.8 (7.40)		
Week 8		65	50.3 (6.58)			63	51.7 (7.37)		
Week 8 chg		65	6.9 (8.21)	6.90 (0.76)		63	8.2 (6.82)	8.21 (0.76)	1.31 (-0.82, 3.44) 0.226 [0.17 (-0.17, 0.52)]
Week 16		60	50.3 (7.73)			58	52.5 (6.53)		
Week 16 chg		60	7.8 (8.51)	7.42 (0.81)		58	8.7 (7.45)	8.81 (0.81)	1.40 (-0.88, 3.67) 0.226 [0.17 (-0.19, 0.54)]
Week 26		56	51.1 (7.56)			57	52.0 (7.51)		
Week 26 chg		56	8.2 (8.52)	7.07 (0.88)		57	8.2 (7.26)	8.60 (0.88)	1.53 (-0.93, 3.99) 0.220 [0.19 (-0.18, 0.56)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8234
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.7.468.4.2: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.7.469.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 26		115	50.7 (9.70)				118	51.1 (7.88)			
Week 26 chg		113	5.6 (8.87)	5.14	(0.66)		114	4.4 (8.31)	4.80	(0.66)	-0.34 (-2.18, 1.50) 0.715 [-0.04 (-0.30, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2697
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.469.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	68 46.4 (11.25)		68	68 46.3 (9.19)		
Week 26		56 50.3 (11.08)			55 51.1 (8.02)		
Week 26 chg		55 3.7 (8.26)	3.62 (0.97)		55 4.1 (7.83)	4.21 (0.97)	0.59 (-2.14, 3.32) 0.669 [0.07 (-0.30, 0.45)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2697
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.469.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 43.4 (11.48)		70	66 46.3 (10.35)		
Week 26		59 51.0 (8.27)			63 51.1 (7.82)		
Week 26 chg		58 7.5 (9.09)	6.53 (0.87)		59 4.6 (8.80)	5.60 (0.87)	-0.93 (-3.39, 1.52) 0.452 [-0.10 (-0.47, 0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2697
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.470.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary											
Total											
Baseline	137	134	44.5 (8.19)			138	134	44.5 (7.83)			
Week 26		115	50.9 (7.60)				118	52.8 (7.38)			
Week 26 chg		113	6.8 (8.15)	6.63	(0.62)		114	8.4 (7.77)	8.47	(0.62)	1.84 (0.11, 3.56) 0.037 [0.23 (-0.03, 0.49)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1545
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.470.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]									
Baseline	70	68	45.7 (8.07)		68	68	45.3 (8.22)		
Week 26		56	50.7 (7.74)			55	53.8 (7.26)		
Week 26 chg		55	5.3 (7.64)	5.19 (0.87)		55	8.3 (8.22)	8.35 (0.87)	3.16 (0.72, 5.60) 0.012 [0.40 (0.02, 0.78)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1545
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.470.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Severe [IGA=4]								
Baseline	67	66 43.2 (8.18)		70	66 43.8 (7.40)			
Week 26		59 51.2 (7.53)			63 52.0 (7.44)			
Week 26 chg		58 8.2 (8.44)	7.99 (0.88)		59 8.4 (7.39)	8.57 (0.87)	0.58 (-1.88, 3.04) [0.07 (-0.29, 0.44)]	0.641

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1545
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.471.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary							
Total							
Baseline	137	134 44.9 (11.42)		138	134 46.3 (9.74)		
Week 16		121 49.5 (10.08)			117 50.1 (9.57)		
Week 16 chg		119 4.4 (8.65)	4.12 (0.70)		113 3.4 (8.59)	3.70 (0.72)	-0.42 (-2.41, 1.56) 0.675 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0687
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.471.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]							
Baseline	70	68 46.4 (11.25)		68	68 46.3 (9.19)		
Week 16		60 49.3 (10.84)			55 51.1 (8.51)		
Week 16 chg		59 2.8 (7.94)	2.67 (0.91)		55 4.0 (7.42)	4.06 (0.95)	1.39 (-1.21, 4.00) 0.292 [0.18 (-0.19, 0.55)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0687
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.471.4.1: Total, Disease severity (IGA), change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 43.4 (11.48)		70	66 46.3 (10.35)		
Week 16		61 49.6 (9.35)			62 49.2 (10.42)		
Week 16 chg		60 5.9 (9.08)	5.45 (1.04)		58 2.9 (9.61)	3.43 (1.06)	-2.02 (-4.98, 0.94) 0.179 [-0.22 (-0.58, 0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0687
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.472.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary									
Total									
Baseline	137	134	44.5 (8.19)		138	134	44.5 (7.83)		
Week 16		121	51.0 (7.75)			117	52.8 (6.79)		
Week 16 chg		119	6.8 (8.15)	6.60 (0.60)		113	8.0 (7.67)	8.20 (0.61)	1.60 (-0.09, 3.28) 0.063 [0.20 (-0.06, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9391
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.472.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Moderate [IGA=3]											
Baseline	70	68	45.7 (8.07)			68	68	45.3 (8.22)			
Week 16		60	51.6 (7.82)				55	53.2 (7.21)			
Week 16 chg		59	5.9 (7.73)	5.78	(0.84)		55	7.2 (7.89)	7.30	(0.87)	1.51 (-0.90, 3.92) 0.216 [0.19 (-0.17, 0.56)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9391
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.472.4.1: Total, Disease severity (IGA), change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Severe [IGA=4]							
Baseline	67	66 43.2 (8.18)		70	66 43.8 (7.40)		
Week 16		61 50.4 (7.69)			62 52.4 (6.43)		
Week 16 chg		60 7.8 (8.51)	7.43 (0.83)		58 8.7 (7.45)	9.08 (0.85)	1.65 (-0.70, 4.01) 0.167 [0.21 (-0.16, 0.57)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9391
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.7.701.3.1: Total, Any TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Moderate [IGA=3]						66	20.1		136	40.2	
Severe [IGA=4]						60	17.8		116	34.8	
Any system organ class											
Any preferred term											
Total	0.6688	0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504
Moderate [IGA=3]		0.3000	1.13 (0.89, 1.43)	1.40 (0.75, 2.62)	7.3 (-6.5, 21.1)	37	(56.1)	79	87	(64.0)	239
Severe [IGA=4]		0.7819	1.02 (0.87, 1.20)	1.12 (0.51, 2.43)	1.8 (-11, 14.3)	47	(78.3)	105	93	(80.2)	265

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 1.7.701.4.1: Total, Any TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.3153	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385
Moderate [IGA=3]		0.5912	1.05 (0.88, 1.25)	1.25 (0.55, 2.85)	3.7 (-9.8, 17.3)	54	(77.1)	211	55	(80.9)	200
Severe [IGA=4]		0.3792	0.92 (0.77, 1.10)	0.70 (0.31, 1.56)	-6.3 (-20, 7.63)	54	(80.6)	212	52	(74.3)	185

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 1.7.702.3.1: Total, Any drug-related TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Moderate [IGA=3]						66	20.1		136	40.2	
Severe [IGA=4]						60	17.8		116	34.8	
Any system organ class											
Any preferred term											
Total	0.7311	0.0023	1.58 (1.16, 2.16)	2.11 (1.30, 3.42)	15.7 (6.11, 25.2)	34	(27.0)	61	108	(42.9)	232
Moderate [IGA=3]		0.0171	1.72 (1.07, 2.77)	2.31 (1.16, 4.64)	16.4 (3.85, 29.0)	15	(22.7)	29	54	(39.7)	121
Severe [IGA=4]		0.0543	1.47 (0.97, 2.21)	1.93 (0.99, 3.78)	14.8 (0.26, 29.3)	19	(31.7)	32	54	(46.6)	111

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 1.7.702.4.1: Total, Any drug-related TEAE, LP0162-1346, 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 + TCS n (%)	E	Tralokinumab Q2W + TCS n (%)	E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Moderate [IGA=3]						70 33.3		68 31.9	
Severe [IGA=4]						67 32.2		70 33.5	
Any system organ class									
Any preferred term									
Total	0.9290	0.2852	1.19 (0.86, 1.65)	1.32 (0.80, 2.17)	6.1 (-5.0, 17.3)	43 (31.4)	94	52 (37.7)	105
Moderate [IGA=3]		0.5047	1.19 (0.71, 2.00)	1.28 (0.62, 2.67)	5.2 (-10, 20.4)	19 (27.1)	39	22 (32.4)	45
Severe [IGA=4]		0.4013	1.20 (0.79, 1.82)	1.34 (0.68, 2.67)	7.0 (-9.3, 23.4)	24 (35.8)	55	30 (42.9)	60

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 1.7.703.3.1: Total, Any TEAE causing permanent discontinuation, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Moderate [IGA=3]						66 20.1		136 40.2	
Severe [IGA=4]						60 17.8		116 34.8	
Any system organ class									
Any preferred term									
Total	0.2765	0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1 (0.8)	1	6 (2.4)	8
Moderate [IGA=3]		0.2222			2.2 (-.25, 4.71)	0 (0.0)	0	3 (2.2)	5
Severe [IGA=4]		0.7028	1.54 (0.17, 14.3)	1.56 (0.16, 15.5)	0.9 (-3.4, 5.21)	1 (1.7)	1	3 (2.6)	3

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 1.7.703.4.1: Total, Any TEAE causing permanent discontinuation, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.0350	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3	(2.2)	4	1	(0.7)	1
Moderate [IGA=3]		0.0855	0.00 (not est.)	0.00 (not est.)	-4.3 (-9.0, 0.46)	3	(4.3)	4	0	(0.0)	0
Severe [IGA=4]		0.3279			1.4 (-1.4, 4.21)	0	(0.0)	0	1	(1.4)	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. TEAE: Treatment emergent adverse events

Table 1.7.704.3.1: Total, Any mild TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Moderate [IGA=3]						66	20.1		136	40.2	
Severe [IGA=4]						60	17.8		116	34.8	
Any system organ class											
Any preferred term											
Total	0.8124	0.1405	1.14 (0.95, 1.36)	1.41 (0.89, 2.23)	7.5 (-2.5, 17.5)	69	(54.8)	132	157	(62.3)	384
Moderate [IGA=3]		0.2081	1.21 (0.89, 1.63)	1.49 (0.81, 2.75)	9.2 (-4.9, 23.3)	29	(43.9)	58	73	(53.7)	173
Severe [IGA=4]		0.4255	1.08 (0.88, 1.33)	1.32 (0.66, 2.64)	5.6 (-8.5, 19.7)	40	(66.7)	74	84	(72.4)	211

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 1.7.704.4.1: Total, Any mild TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.5397	0.9615	1.00 (0.87, 1.16)	1.01 (0.60, 1.71)	0.3 (-10, 10.9)	98	(71.5)	293	99	(71.7)	300
Moderate [IGA=3]		0.6371	1.05 (0.86, 1.28)	1.20 (0.56, 2.55)	3.6 (-11, 18.3)	50	(71.4)	154	51	(75.0)	152
Severe [IGA=4]		0.6959	0.96 (0.77, 1.19)	0.86 (0.42, 1.80)	-3.1 (-18, 12.3)	48	(71.6)	139	48	(68.6)	148

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 1.7.705.3.1: Total, Any moderate TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Moderate [IGA=3]						66	20.1		136	40.2	
Severe [IGA=4]						60	17.8		116	34.8	
Any system organ class											
Any preferred term											
Total	0.1810	0.6376	1.09 (0.75, 1.59)	1.13 (0.68, 1.85)	2.2 (-7.0, 11.4)	30	(23.8)	42	66	(26.2)	113
Moderate [IGA=3]		0.2072	1.43 (0.80, 2.58)	1.59 (0.76, 3.30)	7.9 (-4.0, 19.8)	12	(18.2)	18	36	(26.5)	63
Severe [IGA=4]		0.5604	0.86 (0.53, 1.41)	0.81 (0.41, 1.62)	-4.1 (-18, 9.92)	18	(30.0)	24	30	(25.9)	50

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 1.7.705.4.1: Total, Any moderate TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.1825	0.0876	0.75 (0.53, 1.05)	0.65 (0.39, 1.07)	-9.8 (-21, 1.39)	53	(38.7)	121	40	(29.0)	82
Moderate [IGA=3]		0.8042	0.94 (0.58, 1.53)	0.91 (0.45, 1.87)	-2.0 (-18, 13.6)	23	(32.9)	53	21	(30.9)	46
Severe [IGA=4]		0.0320	0.61 (0.38, 0.97)	0.46 (0.23, 0.94)	-18 (-33, -1.8)	30	(44.8)	68	19	(27.1)	36

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 1.7.706.3.1: Total, Any severe TEAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Moderate [IGA=3]						66	20.1		136	40.2	
Severe [IGA=4]						60	17.8		116	34.8	
Any system organ class											
Any preferred term											
Total	0.9496	0.1738	0.50 (0.18, 1.39)	0.48 (0.16, 1.41)	-2.8 (-7.3, 1.68)	7	(5.6)	10	7	(2.8)	7
Moderate [IGA=3]		0.3383	0.47 (0.10, 2.27)	0.45 (0.09, 2.36)	-2.4 (-8.0, 3.15)	3	(4.5)	3	3	(2.2)	3
Severe [IGA=4]		0.3317	0.52 (0.13, 2.01)	0.50 (0.12, 2.07)	-3.2 (-10, 3.93)	4	(6.7)	7	4	(3.4)	4

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 1.7.706.4.1: Total, Any severe TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.5781	0.1235	0.37 (0.10, 1.38)	0.36 (0.09, 1.39)	-3.7 (-8.3, 0.97)	8	(5.8)	9	3	(2.2)	3
Moderate [IGA=3]		0.4262	0.51 (0.10, 2.72)	0.50 (0.09, 2.82)	-2.8 (-9.5, 3.99)	4	(5.7)	4	2	(2.9)	2
Severe [IGA=4]		0.1580	0.24 (0.03, 2.09)	0.23 (0.02, 2.10)	-4.5 (-11, 1.78)	4	(6.0)	5	1	(1.4)	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. TEAE: Treatment emergent adverse events

Table 1.7.707.3.1: Total, Death, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Moderate [IGA=3]					66	20.1		136	40.2	
Severe [IGA=4]					60	17.8		116	34.8	

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.

Table 1.7.707.4.1: Total, Death, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Moderate [IGA=3]					70	33.3		68	31.9	
Severe [IGA=4]					67	32.2		70	33.5	

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.

Table 1.7.708.3.1: Total, Any TE SAE, LP0162-1339, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Analysis set							
N, Exposure(years)							
Total						126 37.9	252 75.0
Moderate [IGA=3]						66 20.1	136 40.2
Severe [IGA=4]						60 17.8	116 34.8
Any system organ class							
Any preferred term							
Total	0.0539	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4 (3.2) 4	2 (0.8) 2
Moderate [IGA=3]		0.9520	0.93 (0.09, 9.89)	0.93 (0.08, 10.6)	-0.1 (-3.7, 3.44)	1 (1.5) 1	2 (1.5) 2
Severe [IGA=4]		0.0157	0.00 (not est.)	0.00 (not est.)	-5.0 (-11, 0.51)	3 (5.0) 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 1.7.708.4.1: Total, Any TE SAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.3294	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5	(3.6)	9	1	(0.7)	1
Moderate [IGA=3]		0.3261	0.34 (0.04, 3.22)	0.33 (0.03, 3.29)	-2.8 (-8.4, 2.73)	3	(4.3)	5	1	(1.5)	1
Severe [IGA=4]		0.1468	0.00 (not est.)	0.00 (not est.)	-3.0 (-7.1, 1.09)	2	(3.0)	4	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 1.7.709.3.1: Total, Any drug-related TE SAE, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Moderate [IGA=3]					66	20.1		136	40.2	
Severe [IGA=4]					60	17.8		116	34.8	

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 1.7.709.4.1: Total, Any drug-related TE SAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)		3	0 (0.0)		0
Moderate [IGA=3]		0.1618	0.00 (not est.)	0.00 (not est.)	-2.9 (-6.8, 1.05)	2 (2.9)		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 1.7.710.3.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Moderate [IGA=3]					66	20.1		136	40.2	
Severe [IGA=4]					60	17.8		116	34.8	

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 1.7.710.4.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Moderate [IGA=3]						70 33.3		68 31.9	
Severe [IGA=4]						67 32.2		70 33.5	
Any system organ class									
Any preferred term									
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)	3	0 (0.0)	0
Moderate [IGA=3]		0.1618	0.00 (not est.)	0.00 (not est.)	-2.9 (-6.8, 1.05)	2 (2.9)	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 1.7.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Moderate [IGA=3]						66	20.1		136	40.2	
Severe [IGA=4]						60	17.8		116	34.8	
Any system organ class											
Any preferred term											
Total	0.6688	0.3262	1.07 (0.93, 1.23)	1.28 (0.79, 2.08)	4.7 (-4.7, 14.1)	84	(66.7)	184	180	(71.4)	504
Moderate [IGA=3]		0.3000	1.13 (0.89, 1.43)	1.40 (0.75, 2.62)	7.3 (-6.5, 21.1)	37	(56.1)	79	87	(64.0)	239
Severe [IGA=4]		0.7819	1.02 (0.87, 1.20)	1.12 (0.51, 2.43)	1.8 (-11, 14.3)	47	(78.3)	105	93	(80.2)	265
Eye disorders											
Any											
Total	0.5207	0.0191	3.12 (1.12, 8.68)	3.50 (1.17, 10.5)	6.7 (2.02, 11.5)	4	(3.2)	5	25	(9.9)	29
Moderate [IGA=3]		0.0670	5.23 (0.70, 39.0)	5.69 (0.71, 45.4)	6.5 (1.07, 11.9)	1	(1.5)	2	11	(8.1)	13
Severe [IGA=4]		0.1295	2.40 (0.73, 7.88)	2.69 (0.72, 9.95)	7.0 (-.93, 14.9)	3	(5.0)	3	14	(12.1)	16
Gastrointestinal disorders											
Any											
Total	0.9260	0.2711	1.49 (0.73, 3.06)	1.55 (0.71, 3.40)	3.5 (-2.4, 9.43)	9	(7.1)	10	27	(10.7)	30
General disorders and administration site conditions											
Any											
Total	0.1994	0.0459	1.81 (0.99, 3.31)	1.99 (1.00, 3.94)	7.7 (0.80, 14.6)	12	(9.5)	13	43	(17.1)	66
Moderate [IGA=3]		0.0323	3.24 (1.00, 10.5)	3.60 (1.04, 12.5)	10.2 (2.40, 18.1)	3	(4.5)	4	20	(14.7)	38
Severe [IGA=4]		0.4340	1.32 (0.65, 2.68)	1.40 (0.60, 3.25)	4.8 (-6.8, 16.4)	9	(15.0)	9	23	(19.8)	28

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 1.7.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Injection site reaction									
Total	1.0000	0.0026			6.7 (3.63, 9.81)	0 (0.0)	0	17 (6.7)	30
Moderate [IGA=3]		0.0047			11.2 (5.86, 16.4)	0 (0.0)	0	15 (11.0)	28
Severe [IGA=4]		0.3014			1.7 (-.64, 4.12)	0 (0.0)	0	2 (1.7)	2
Infections and infestations									
Any									
Total	0.9889	0.0346	1.30 (1.01, 1.69)	1.63 (1.03, 2.56)	11.1 (0.97, 21.2)	46 (36.5)	72	120 (47.6)	186
Moderate [IGA=3]		0.1383	1.36 (0.89, 2.09)	1.62 (0.85, 3.08)	10.4 (-3.0, 23.9)	19 (28.8)	28	54 (39.7)	87
Severe [IGA=4]		0.1320	1.26 (0.92, 1.73)	1.64 (0.86, 3.10)	11.8 (-3.4, 27.0)	27 (45.0)	44	66 (56.9)	99
Upper respiratory tract infection									
Total	0.4251	0.3271	1.55 (0.64, 3.79)	1.60 (0.62, 4.11)	2.6 (-2.3, 7.57)	6 (4.8)	7	19 (7.5)	21
Conjunctivitis									
Total	0.4602	0.0087	3.46 (1.25, 9.58)	3.95 (1.33, 11.7)	7.8 (2.97, 12.7)	4 (3.2)	4	28 (11.1)	32
Moderate [IGA=3]		0.0345	6.04 (0.82, 44.3)	7.17 (0.90, 57.4)	7.8 (2.14, 13.4)	1 (1.5)	1	13 (9.6)	16
Severe [IGA=4]		0.1003	2.57 (0.78, 8.46)	2.87 (0.79, 10.5)	7.9 (-.25, 16.0)	3 (5.0)	3	15 (12.9)	16
Viral upper respiratory tract infection									
Total	0.6560	0.0363	1.75 (1.02, 3.01)	2.00 (1.04, 3.85)	8.3 (1.16, 15.4)	14 (11.1)	18	49 (19.4)	64
Moderate [IGA=3]		0.0975	2.11 (0.84, 5.31)	2.34 (0.84, 6.50)	8.4 (-.42, 17.3)	5 (7.6)	5	22 (16.2)	27
Severe [IGA=4]		0.1872	1.54 (0.79, 3.00)	1.77 (0.75, 4.17)	8.2 (-3.3, 19.6)	9 (15.0)	13	27 (23.3)	37
Injury, poisoning and procedural complications									
Any									
Total	0.1172	0.5974	1.31 (0.48, 3.60)	1.32 (0.46, 3.77)	1.2 (-3.2, 5.63)	5 (4.0)	6	13 (5.2)	14
Musculoskeletal and connective tissue disorders									
Any									

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 1.7.711.3.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total	0.4729	0.2269	1.79 (0.68, 4.68)	1.86 (0.67, 5.14)	3.2 (-1.5, 7.81)	5	(4.0)	6	18	(7.1)	20
Nervous system disorders											
Any											
Total	0.5278	0.1130	1.80 (0.85, 3.78)	1.93 (0.85, 4.40)	5.1 (-.65, 10.8)	8	(6.3)	11	29	(11.5)	37
Headache											
Total	0.7508	0.1663	1.81 (0.77, 4.29)	1.93 (0.75, 4.95)	3.9 (-1.1, 8.91)	6	(4.8)	9	22	(8.7)	26
Respiratory, thoracic and mediastinal disorders											
Any											
Total	0.1079	0.5541	1.21 (0.64, 2.28)	1.24 (0.61, 2.50)	2.0 (-4.5, 8.52)	12	(9.5)	14	29	(11.5)	39
Skin and subcutaneous tissue disorders											
Any											
Total	0.4032	0.0628	0.63 (0.38, 1.02)	0.58 (0.32, 1.03)	-7.1 (-15, 0.81)	24	(19.0)	28	30	(11.9)	36
Dermatitis atopic											
Total	0.2085	0.0125	0.30 (0.11, 0.82)	0.28 (0.10, 0.80)	-5.5 (-11, -.44)	10	(7.9)	12	6	(2.4)	8
Moderate [IGA=3]		0.7184	0.72 (0.12, 4.24)	0.72 (0.12, 4.40)	-0.8 (-5.7, 3.97)	2	(3.0)	2	3	(2.2)	5
Severe [IGA=4]		0.0055	0.19 (0.05, 0.70)	0.17 (0.04, 0.68)	-11 (-20, -1.7)	8	(13.3)	10	3	(2.6)	3

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 1.7.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.3153	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385
Moderate [IGA=3]		0.5912	1.05 (0.88, 1.25)	1.25 (0.55, 2.85)	3.7 (-9.8, 17.3)	54	(77.1)	211	55	(80.9)	200
Severe [IGA=4]		0.3792	0.92 (0.77, 1.10)	0.70 (0.31, 1.56)	-6.3 (-20, 7.63)	54	(80.6)	212	52	(74.3)	185
Eye disorders											
Any											
Total	0.4755	0.2842	1.54 (0.69, 3.44)	1.61 (0.67, 3.84)	3.6 (-3.0, 10.1)	9	(6.6)	14	14	(10.1)	17
Gastrointestinal disorders											
Any											
Total	0.7613	0.8349	0.93 (0.48, 1.81)	0.92 (0.44, 1.95)	-0.8 (-8.3, 6.68)	16	(11.7)	23	15	(10.9)	18
General disorders and administration site conditions											
Any											
Total	0.7858	0.1576	1.59 (0.83, 3.03)	1.70 (0.81, 3.57)	5.6 (-2.1, 13.3)	13	(9.5)	16	21	(15.2)	27
Infections and infestations											
Any											
Total	0.9655	0.2533	0.89 (0.72, 1.09)	0.76 (0.47, 1.22)	-6.8 (-18, 4.82)	83	(60.6)	152	74	(53.6)	144

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 1.7.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Upper respiratory tract infection											
Total	0.5817	0.9930	1.00 (0.43, 2.31)	1.00 (0.40, 2.47)	-0.0 (-6.2, 6.12)	10	(7.3)	11	10	(7.2)	12
Viral upper respiratory tract infection											
Total	0.3392	0.7928	1.05 (0.71, 1.57)	1.08 (0.63, 1.84)	1.4 (-9.0, 11.8)	35	(25.5)	46	37	(26.8)	53
Injury, poisoning and procedural complications											
Any											
Total	0.0391	0.5243	1.29 (0.59, 2.84)	1.32 (0.56, 3.08)	2.1 (-4.5, 8.74)	10	(7.3)	12	13	(9.4)	16
Musculoskeletal and connective tissue disorders											
Any											
Total	0.3368	0.4116	1.27 (0.72, 2.24)	1.32 (0.68, 2.57)	3.5 (-4.9, 12.0)	18	(13.1)	28	23	(16.7)	25
Nervous system disorders											
Any											
Total	0.1879	0.6516	1.13 (0.66, 1.94)	1.16 (0.61, 2.20)	2.0 (-6.7, 10.8)	21	(15.3)	31	24	(17.4)	33
Headache											
Total	0.3072	0.1506	1.61 (0.84, 3.09)	1.71 (0.82, 3.57)	5.7 (-2.0, 13.5)	13	(9.5)	18	21	(15.2)	25
Respiratory, thoracic and mediastinal disorders											
Any											
Total	0.8724	0.0335	0.55 (0.31, 0.96)	0.49 (0.25, 0.95)	-9.5 (-18, -.84)	29	(21.2)	38	16	(11.6)	21
Moderate [IGA=3]		0.1438	0.58 (0.27, 1.22)	0.51 (0.21, 1.26)	-9.6 (-22, 3.09)	16	(22.9)	20	9	(13.2)	13
Severe [IGA=4]		0.1206	0.52 (0.22, 1.21)	0.46 (0.17, 1.24)	-9.4 (-21, 2.39)	13	(19.4)	18	7	(10.0)	8
Skin and subcutaneous tissue disorders											
Any											

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 1.7.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Total	0.3470	0.1365	0.71 (0.46, 1.12)	0.65 (0.37, 1.15)	-7.5 (-17, 2.33)	36 (26.3)	59	26 (18.8)	44
Dermatitis atopic									
Total	0.9171	0.0498	0.44 (0.19, 1.03)	0.41 (0.16, 1.02)	-6.6 (-13, -.07)	16 (11.7)	26	7 (5.1)	11
Moderate [IGA=3]		0.1623	0.46 (0.15, 1.42)	0.42 (0.12, 1.45)	-7.0 (-17, 2.66)	9 (12.9)	15	4 (5.9)	8
Severe [IGA=4]		0.1673	0.41 (0.11, 1.52)	0.38 (0.09, 1.55)	-6.2 (-15, 2.56)	7 (10.4)	11	3 (4.3)	3
Vascular disorders									
Any									
Total	0.5062	0.0596	0.36 (0.12, 1.10)	0.34 (0.10, 1.09)	-5.2 (-11, 0.16)	11 (8.0)	12	4 (2.9)	6

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 1.7.712.3.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Moderate [IGA=3]						66 20.1		136 40.2	
Severe [IGA=4]						60 17.8		116 34.8	
Any system organ class									
Any preferred term									
Total	0.0539	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4 (3.2)	4	2 (0.8)	2
Moderate [IGA=3]		0.9520	0.93 (0.09, 9.89)	0.93 (0.08, 10.6)	-0.1 (-3.7, 3.44)	1 (1.5)	1	2 (1.5)	2
Severe [IGA=4]		0.0157	0.00 (not est.)	0.00 (not est.)	-5.0 (-11, 0.51)	3 (5.0)	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 1.7.712.4.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Moderate [IGA=3]						70 33.3		68 31.9	
Severe [IGA=4]						67 32.2		70 33.5	
Any system organ class									
Any preferred term									
Total	0.3294	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5 (3.6)	9	1 (0.7)	1
Moderate [IGA=3]		0.3261	0.34 (0.04, 3.22)	0.33 (0.03, 3.29)	-2.8 (-8.4, 2.73)	3 (4.3)	5	1 (1.5)	1
Severe [IGA=4]		0.1468	0.00 (not est.)	0.00 (not est.)	-3.0 (-7.1, 1.09)	2 (3.0)	4	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 1.7.713.3.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Moderate [IGA=3]						66 20.1		136 40.2	
Severe [IGA=4]						60 17.8		116 34.8	
Any system organ class									
Any preferred term									
Total	0.2765	0.2763	3.04 (0.37, 25.0)	3.12 (0.37, 26.6)	1.6 (-.82, 4.03)	1 (0.8)	1	6 (2.4)	8
Moderate [IGA=3]		0.2222			2.2 (-.25, 4.71)	0 (0.0)	0	3 (2.2)	5
Severe [IGA=4]		0.7028	1.54 (0.17, 14.3)	1.56 (0.16, 15.5)	0.9 (-3.4, 5.21)	1 (1.7)	1	3 (2.6)	3
General disorders and administration site conditions									
Any									
Total	1.0000	0.3123			0.8 (-.30, 1.91)	0 (0.0)	0	2 (0.8)	2
Injection site reaction									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Hernia									
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0 (0.0)	0	1 (0.4)	1
Infections and infestations									
Any									
Total	1.0000	0.2229			1.2 (-.15, 2.52)	0 (0.0)	0	3 (1.2)	3
Influenza									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Otitis media									
Total	Not est.	0.4954			0.4 (-.38, 1.14)	0 (0.0)	0	1 (0.4)	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. TE SAE: Treatment emergent serious adverse events

Table 1.7.713.3.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Conjunctivitis									
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0 (0.0)	0	1 (0.4)	1
Musculoskeletal and connective tissue disorders									
Any									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Myalgia									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Psychiatric disorders									
Any									
Total	1.0000	0.3123			0.8 (-.30, 1.91)	0 (0.0)	0	2 (0.8)	2
Mood altered									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Anxiety									
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0 (0.0)	0	1 (0.4)	1
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Dermatitis atopic									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	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. TE SAE: Treatment emergent serious adverse events

Table 1.7.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.0350	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3	(2.2)	4	1	(0.7)	1
Moderate [IGA=3]		0.0855	0.00 (not est.)	0.00 (not est.)	-4.3 (-9.0, 0.46)	3	(4.3)	4	0	(0.0)	0
Severe [IGA=4]		0.3279			1.4 (-1.4, 4.21)	0	(0.0)	0	1	(1.4)	1
General disorders and administration site conditions											
Any											
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0	(0.0)	0	1	(0.7)	1
Injection site pain											
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0	(0.0)	0	1	(0.7)	1
Nervous system disorders											
Any											
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1	(0.7)	1	0	(0.0)	0
Cerebrovascular accident											
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1	(0.7)	1	0	(0.0)	0
Psychiatric disorders											
Any											
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1	(0.7)	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

Table 1.7.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCSE n (%)	Placebo + TCSE	Tralokinumab Q2W + TCSE n (%)	Tralokinumab Q2W + TCSE
Depressed mood									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Suicidal ideation									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis atopic									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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. TE SAE: Treatment emergent serious adverse events

Table 1.7.714.3.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Moderate [IGA=3]						66	20.1		136	40.2	
Severe [IGA=4]						60	17.8		116	34.8	
Any system organ class											
Any preferred term											
Total	0.9268	0.0185	2.40 (1.10, 5.22)	2.71 (1.15, 6.37)	7.8 (2.10, 13.5)	7	(5.6)	7	34	(13.5)	39
Moderate [IGA=3]		0.1347	2.35 (0.71, 7.79)	2.57 (0.71, 9.25)	6.1 (-1.0, 13.3)	3	(4.5)	3	15	(11.0)	19
Severe [IGA=4]		0.0686	2.44 (0.88, 6.76)	2.83 (0.90, 8.92)	9.6 (0.58, 18.7)	4	(6.7)	4	19	(16.4)	20
Eye disorders											
Any											
Total	0.6260	0.6213	1.48 (0.31, 7.12)	1.50 (0.30, 7.61)	0.8 (-2.1, 3.64)	2	(1.6)	2	6	(2.4)	7
Keratitis											
Total	Not est.	0.4738			0.4 (-.38, 1.19)	0	(0.0)	0	1	(0.4)	1
Conjunctivitis allergic											
Total	0.7606	0.8018	1.23 (0.25, 6.16)	1.24 (0.23, 6.53)	0.4 (-2.4, 3.13)	2	(1.6)	2	5	(2.0)	6
Infections and infestations											
Any											
Total	0.8743	0.0205	2.77 (1.10, 7.00)	3.04 (1.14, 8.11)	7.0 (1.91, 12.1)	5	(4.0)	5	28	(11.1)	32
Moderate [IGA=3]		0.1011	3.06 (0.70, 13.4)	3.28 (0.73, 14.7)	6.3 (-.14, 12.7)	2	(3.0)	2	13	(9.6)	16
Severe [IGA=4]		0.1003	2.57 (0.78, 8.46)	2.87 (0.79, 10.5)	7.9 (-.25, 16.0)	3	(5.0)	3	15	(12.9)	16
Conjunctivitis viral											
Total	Not est.	0.1605	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1	(0.8)	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

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Table 1.7.714.3.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Conjunctivitis											
Total	0.4602	0.0087	3.46 (1.25, 9.58)	3.95 (1.33, 11.7)	7.8 (2.97, 12.7)	4	(3.2)	4	28	(11.1)	32
Moderate [IGA=3]		0.0345	6.04 (0.82, 44.3)	7.17 (0.90, 57.4)	7.8 (2.14, 13.4)	1	(1.5)	1	13	(9.6)	16
Severe [IGA=4]		0.1003	2.57 (0.78, 8.46)	2.87 (0.79, 10.5)	7.9 (-.25, 16.0)	3	(5.0)	3	15	(12.9)	16

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 1.7.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.9378	0.0780	2.14 (0.90, 5.07)	2.28 (0.90, 5.77)	5.8 (-.58, 12.2)	7	(5.1)	9	15	(10.9)	17
Moderate [IGA=3]		0.2089	2.06 (0.65, 6.52)	2.20 (0.63, 7.68)	6.1 (-3.3, 15.4)	4	(5.7)	5	8	(11.8)	9
Severe [IGA=4]		0.2159	2.23 (0.60, 8.28)	2.37 (0.59, 9.58)	5.5 (-3.1, 14.1)	3	(4.5)	4	7	(10.0)	8
Eye disorders											
Any											
Total	0.1324	0.1593	2.23 (0.71, 7.03)	2.30 (0.70, 7.57)	3.6 (-1.4, 8.64)	4	(2.9)	4	9	(6.5)	11
Atopic keratoconjunctivitis											
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0	(0.0)	0	1	(0.7)	1
Lacrimation increased											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Exposure keratitis											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Conjunctivitis allergic											
Total	0.1636	0.5286	1.48 (0.43, 5.11)	1.50 (0.42, 5.40)	1.4 (-3.0, 5.88)	4	(2.9)	4	6	(4.3)	8
Infections and infestations											
Any											
Total	0.2005	0.5286	1.49 (0.43, 5.24)	1.51 (0.42, 5.49)	1.4 (-3.0, 5.84)	4	(2.9)	5	6	(4.3)	6

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

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Table 1.7.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Keratitis viral									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Herpes ophthalmic									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Conjunctivitis									
Total	0.6990	0.1591	2.96 (0.61, 14.5)	3.05 (0.60, 15.4)	2.9 (-1.1, 6.81)	2 (1.5)	3	6 (4.3)	6

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 1.7.715.3.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Moderate [IGA=3]					66	20.1		136	40.2	
Severe [IGA=4]					60	17.8		116	34.8	

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 1.7.715.4.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Moderate [IGA=3]					70	33.3		68	31.9	
Severe [IGA=4]					67	32.2		70	33.5	

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 1.7.716.3.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Moderate [IGA=3]						66 20.1		136 40.2	
Severe [IGA=4]						60 17.8		116 34.8	
Any system organ class									
Any preferred term									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	1
Moderate [IGA=3]		0.1424	0.00 (not est.)	0.00 (not est.)	-1.5 (-4.5, 1.43)	1 (1.5)	1	0 (0.0)	0
Severe [IGA=4]		0.4738			0.9 (-.82, 2.54)	0 (0.0)	0	1 (0.9)	1
Infections and infestations									
Any									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	1
Eczema herpeticum									
Total	Not est.	0.6048	0.50 (0.03, 7.42)	0.50 (0.03, 7.68)	-0.4 (-2.2, 1.35)	1 (0.8)	1	1 (0.4)	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 1.7.716.4.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	2
Moderate [IGA=3]		0.3103			1.5 (-1.4, 4.33)	0	(0.0)	0	1	(1.5)	2
Infections and infestations											
Any											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	2
Eczema herpeticum											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	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 1.7.717.3.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Moderate [IGA=3]					66	20.1		136	40.2	
Severe [IGA=4]					60	17.8		116	34.8	

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 1.7.717.4.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Moderate [IGA=3]					70	33.3		68	31.9	
Severe [IGA=4]					67	32.2		70	33.5	

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 1.7.718.3.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Moderate [IGA=3]					66	20.1		136	40.2	
Severe [IGA=4]					60	17.8		116	34.8	

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 1.7.718.4.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Moderate [IGA=3]					70	33.3		68	31.9	
Severe [IGA=4]					67	32.2		70	33.5	

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 1.7.719.3.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					126	37.9		252	75.0	
Moderate [IGA=3]					66	20.1		136	40.2	
Severe [IGA=4]					60	17.8		116	34.8	

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 1.7.719.4.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Moderate [IGA=3]					70	33.3		68	31.9	
Severe [IGA=4]					67	32.2		70	33.5	

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 1.7.720.3.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Moderate [IGA=3]						66 20.1		136 40.2	
Severe [IGA=4]						60 17.8		116 34.8	
Any system organ class									
Any preferred term									
Total	0.8365	0.0327	0.29 (0.09, 0.97)	0.27 (0.08, 0.96)	-3.9 (-8.2, 0.34)	7 (5.6)	9	4 (1.6)	4
Moderate [IGA=3]		0.1933	0.33 (0.06, 1.91)	0.32 (0.05, 1.94)	-3.1 (-8.5, 2.36)	3 (4.5)	3	2 (1.5)	2
Severe [IGA=4]		0.0883	0.26 (0.05, 1.37)	0.24 (0.04, 1.37)	-4.9 (-12, 1.79)	4 (6.7)	6	2 (1.7)	2
Infections and infestations									
Any									
Total	0.8365	0.0327	0.29 (0.09, 0.97)	0.27 (0.08, 0.96)	-3.9 (-8.2, 0.34)	7 (5.6)	9	4 (1.6)	4
Moderate [IGA=3]		0.1933	0.33 (0.06, 1.91)	0.32 (0.05, 1.94)	-3.1 (-8.5, 2.36)	3 (4.5)	3	2 (1.5)	2
Severe [IGA=4]		0.0883	0.26 (0.05, 1.37)	0.24 (0.04, 1.37)	-4.9 (-12, 1.79)	4 (6.7)	6	2 (1.7)	2
Infected dermal cyst									
Total	Not est.	0.4761			0.4 (-.38, 1.18)	0 (0.0)	0	1 (0.4)	1
Cellulitis									
Total	0.2972	0.9983	1.00 (0.09, 11.2)	1.00 (0.09, 11.1)	-0.0 (-1.9, 1.90)	1 (0.8)	1	2 (0.8)	2
Paronychia									
Total	Not est.	0.1675	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Impetigo									
Total	Not est.	0.6369	0.52 (0.03, 8.40)	0.52 (0.03, 8.30)	-0.4 (-2.1, 1.35)	1 (0.8)	1	1 (0.4)	1
Dermatitis infected									
Total	1.0000	0.0048	0.00 (not est.)	0.00 (not est.)	-3.2 (-6.2, -.11)	4 (3.2)	6	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

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Table 1.7.720.3.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Moderate [IGA=3]		0.0424	0.00 (not est.)	0.00 (not est.)	-3.0 (-7.2, 1.11)	2 (3.0)	2	0 (0.0)	0
Severe [IGA=4]		0.0496	0.00 (not est.)	0.00 (not est.)	-3.3 (-7.9, 1.21)	2 (3.3)	4	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 1.7.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Moderate [IGA=3]						70 33.3		68 31.9	
Severe [IGA=4]						67 32.2		70 33.5	
Any system organ class									
Any preferred term									
Total	0.1885	0.0178	0.12 (0.02, 0.99)	0.12 (0.01, 0.96)	-5.1 (-9.3, -.93)	8 (5.8)	12	1 (0.7)	1
Moderate [IGA=3]		0.0253	0.00 (not est.)	0.00 (not est.)	-7.1 (-13, -1.1)	5 (7.1)	7	0 (0.0)	0
Severe [IGA=4]		0.2911	0.32 (0.03, 2.99)	0.31 (0.03, 3.05)	-3.0 (-8.7, 2.63)	3 (4.5)	5	1 (1.4)	1
Infections and infestations									
Any									
Total	0.2253	0.0311	0.14 (0.02, 1.15)	0.13 (0.02, 1.12)	-4.4 (-8.3, -.44)	7 (5.1)	11	1 (0.7)	1
Moderate [IGA=3]		0.0462	0.00 (not est.)	0.00 (not est.)	-5.7 (-11, -.28)	4 (5.7)	6	0 (0.0)	0
Severe [IGA=4]		0.2911	0.32 (0.03, 2.99)	0.31 (0.03, 3.05)	-3.0 (-8.7, 2.63)	3 (4.5)	5	1 (1.4)	1
Staphylococcal skin infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Cellulitis									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Wound infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Oral herpes									
Total	Not est.	0.3067	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.2, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis infected									
Total	0.2880	0.1718	0.24 (0.03, 2.19)	0.24 (0.03, 2.19)	-2.2 (-5.4, 0.94)	4 (2.9)	7	1 (0.7)	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

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Table 1.7.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Skin and subcutaneous tissue disorders							
Any							
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7) 1	0 (0.0) 0
Hand dermatitis							
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7) 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 1.7.721.3.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Moderate [IGA=3]						66 20.1		136 40.2	
Severe [IGA=4]						60 17.8		116 34.8	
Any system organ class									
Any preferred term									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Severe [IGA=4]		0.1627	0.00 (not est.)	0.00 (not est.)	-1.7 (-4.9, 1.57)	1 (1.7)	1	0 (0.0)	0
Infections and infestations									
Any									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	1	0 (0.0)	0
Dermatitis infected									
Total	Not est.	0.1627	0.00 (not est.)	0.00 (not est.)	-0.8 (-2.3, 0.76)	1 (0.8)	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. TESAESI: Treatment emergent serious adverse events of special interest

Table 1.7.721.4.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Moderate [IGA=3]					70	33.3		68	31.9	
Severe [IGA=4]					67	32.2		70	33.5	

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 1.7.722.3.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						126	37.9		252	75.0	
Moderate [IGA=3]						66	20.1		136	40.2	
Severe [IGA=4]						60	17.8		116	34.8	
Any system organ class											
Any preferred term											
Total	0.9200	0.1972	1.10 (0.95, 1.27)	1.37 (0.85, 2.22)	6.2 (-3.3, 15.8)	81	(64.3)	168	178	(70.6)	494
Moderate [IGA=3]		0.3525	1.12 (0.88, 1.42)	1.35 (0.72, 2.52)	6.6 (-7.3, 20.4)	37	(56.1)	76	86	(63.2)	232
Severe [IGA=4]		0.3683	1.08 (0.91, 1.29)	1.41 (0.67, 2.97)	5.9 (-7.2, 19.0)	44	(73.3)	92	92	(79.3)	262

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 1.7.722.4.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.4853	0.8030	0.98 (0.87, 1.12)	0.93 (0.53, 1.64)	-1.3 (-11, 8.62)	107	(78.1)	391	106	(76.8)	361
Moderate [IGA=3]		0.7475	1.03 (0.86, 1.23)	1.14 (0.51, 2.57)	2.3 (-11, 16.0)	54	(77.1)	193	54	(79.4)	187
Severe [IGA=4]		0.5067	0.94 (0.78, 1.13)	0.76 (0.34, 1.69)	-4.8 (-19, 9.31)	53	(79.1)	198	52	(74.3)	174

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 1.7.723.3.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1339, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						126 37.9		252 75.0	
Moderate [IGA=3]						66 20.1		136 40.2	
Severe [IGA=4]						60 17.8		116 34.8	
Any system organ class									
Any preferred term									
Total	0.0539	0.0765	0.24 (0.04, 1.34)	0.23 (0.04, 1.32)	-2.4 (-5.7, 0.83)	4 (3.2)	4	2 (0.8)	2
Moderate [IGA=3]		0.9520	0.93 (0.09, 9.89)	0.93 (0.08, 10.6)	-0.1 (-3.7, 3.44)	1 (1.5)	1	2 (1.5)	2
Severe [IGA=4]		0.0157	0.00 (not est.)	0.00 (not est.)	-5.0 (-11, 0.51)	3 (5.0)	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. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.7.723.4.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Moderate [IGA=3]						70	33.3		68	31.9	
Severe [IGA=4]						67	32.2		70	33.5	
Any system organ class											
Any preferred term											
Total	0.3294	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5	(3.6)	8	1	(0.7)	1
Moderate [IGA=3]		0.3261	0.34 (0.04, 3.22)	0.33 (0.03, 3.29)	-2.8 (-8.4, 2.73)	3	(4.3)	5	1	(1.5)	1
Severe [IGA=4]		0.1468	0.00 (not est.)	0.00 (not est.)	-3.0 (-7.1, 1.09)	2	(3.0)	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. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.16.101.4.1.1: Total, Germany, Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	18	22
Age (years)		
Mean (sd)	42.8 (17.9)	45.2 (15.6)
Gender		
Female	6 (33.3%)	7 (31.8%)
Male	12 (66.7%)	15 (68.2%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	27.7 (5.6)	25.8 (4.5)
Race		
White	18 (100%)	21 (95.5%)
Other		1 (4.5%)
Geographic region		
Europe	18 (100%)	22 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	43.7 (22.0)	46.8 (21.0)
Duration of AD (years)		
Mean (sd)	24.9 (11.4)	32.9 (15.7)
Eczema Area and Severity Index (EASI)		
Mean (sd)	28.6 (7.7)	28.9 (8.0)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	12 (66.7%)	13 (59.1%)
Severe [IGA=4]	6 (33.3%)	9 (40.9%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.9 (1.3)	7.1 (1.4)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.3 (1.7)	6.1 (1.8)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	69.5 (9.2)	67.2 (6.1)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	16.0 (8.0)	16.1 (5.2)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	12.6 (6.2)	11.6 (5.0)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	46.9 (24.5)	47.8 (17.2)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.564 (0.25)	0.661 (0.17)
Patients that have tried systemic corticosteroids (%)		
No	8 (44.4%)	10 (45.5%)
Yes	10 (55.6%)	12 (54.5%)
Previous number of treatments with systemic immunosuppressants*		
0	4 (22.2%)	8 (36.4%)
1	11 (61.1%)	13 (59.1%)
2	2 (11.1%)	1 (4.5%)
4	1 (5.6%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.16.101.4.2.1: Total, Rest of World, Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	119	116
Age (years)		
Mean (sd)	35.1 (12.7)	35.2 (13.9)
Gender		
Female	48 (40.3%)	50 (43.1%)
Male	71 (59.7%)	66 (56.9%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	25.5 (5.8)	25.0 (4.2)
Race		
Asian	1 (0.8%)	
Black	1 (0.8%)	
White	117 (98.3%)	114 (98.3%)
Other		2 (1.7%)
Geographic region		
Europe	119 (100%)	116 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	56.9 (22.6)	55.4 (21.8)
Duration of AD (years)		
Mean (sd)	25.4 (14.5)	26.0 (13.2)
Eczema Area and Severity Index (EASI)		
Mean (sd)	34.6 (14.0)	32.7 (12.0)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	58 (48.7%)	55 (47.4%)
Severe [IGA=4]	61 (51.3%)	61 (52.6%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.4 (1.4)	7.3 (1.5)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.8 (1.6)	6.3 (2.2)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	71.0 (13.3)	70.7 (12.8)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	16.4 (6.1)	15.8 (6.8)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	11.6 (7.7)	10.5 (6.7)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	53.3 (21.6)	58.3 (20.0)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.595 (0.24)	0.629 (0.23)
Patients that have tried systemic corticosteroids (%)		
No	38 (31.9%)	31 (26.7%)
Yes	81 (68.1%)	85 (73.3%)
Previous number of treatments with systemic immunosuppressants*		
0	19 (16.0%)	14 (12.1%)
1	67 (56.3%)	72 (62.1%)
2	25 (21.0%)	21 (18.1%)
3	6 (5.0%)	8 (6.9%)
4	1 (0.8%)	1 (0.9%)
5	1 (0.8%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.16.102.4.1: Total, Germany, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Germany				
Analysis set				
N	18		22	
Blood and lymphatic system disorders				
Lymphopenia			1	(4.5)
Cardiac disorders				
Atrial fibrillation			2	(9.1)
Cardiomyopathy	1	(5.6)		
Atrioventricular block first degree			1	(4.5)
Congenital, familial and genetic disorders				
Von Willebrand's disease			1	(4.5)
Ear and labyrinth disorders				
Deafness	1	(5.6)		
Endocrine disorders				
Hypothyroidism			2	(9.1)
Eye disorders				
Conjunctivitis allergic	8	(44.4)	7	(31.8)
Cataract			2	(9.1)
Dry eye	1	(5.6)		
Blepharitis			1	(4.5)
Retinal degeneration			1	(4.5)
Gastrointestinal disorders				
Gastrooesophageal reflux disease			2	(9.1)
Chronic gastritis	1	(5.6)	1	(4.5)
Hiatus hernia	1	(5.6)		
Barrett's oesophagus			1	(4.5)
Dyspepsia			1	(4.5)
Immune system disorders				
Seasonal allergy	10	(55.6)	13	(59.1)
Food allergy	5	(27.8)	7	(31.8)
Allergy to animal	3	(16.7)	3	(13.6)
Mite allergy	3	(16.7)	3	(13.6)
Hypersensitivity	2	(11.1)	1	(4.5)
Allergy to metals			2	(9.1)
Drug hypersensitivity	1	(5.6)	2	(9.1)
Allergy to plants	1	(5.6)		
Multiple allergies	1	(5.6)		
Allergy to chemicals			1	(4.5)
Milk allergy			1	(4.5)
Infections and infestations				
Herpes simplex	2	(11.1)	2	(9.1)
Epididymitis			1	(4.5)
Injury, poisoning and procedural complications				
Joint injury			1	(4.5)
Metabolism and nutrition disorders				
Gout	2	(11.1)		
Diabetes mellitus			2	(9.1)
Dyslipidaemia	1	(5.6)		
Hypercholesterolaemia	1	(5.6)		
Hyperlipidaemia	1	(5.6)	1	(4.5)
Hyperuricaemia	1	(5.6)		
Iron deficiency	1	(5.6)		
Lactose intolerance	1	(5.6)		
Obesity	1	(5.6)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.16.102.4.1: Total, Germany, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Germany				
Metabolism and nutrition disorders				
Obesity			1	(4.5)
Type 2 diabetes mellitus	1	(5.6)		
Musculoskeletal and connective tissue disorders				
Osteoarthritis	1	(5.6)	2	(9.1)
Arthralgia	1	(5.6)		
Intervertebral disc protrusion	1	(5.6)	1	(4.5)
Osteoporosis	1	(5.6)	1	(4.5)
Back pain			1	(4.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Melanocytic naevus			3	(13.6)
Fibroma			1	(4.5)
Nervous system disorders				
Headache	1	(5.6)	2	(9.1)
Hypertonia			2	(9.1)
Restless legs syndrome	1	(5.6)		
Psychiatric disorders				
Depression	2	(11.1)	1	(4.5)
Sleep disorder	1	(5.6)		
Attention deficit/hyperactivity disorder			1	(4.5)
Renal and urinary disorders				
Incontinence	1	(5.6)		
Proteinuria	1	(5.6)		
Renal failure	1	(5.6)		
Nephrolithiasis			1	(4.5)
Reproductive system and breast disorders				
Benign prostatic hyperplasia	1	(5.6)		
Menstrual disorder	1	(5.6)		
Respiratory, thoracic and mediastinal disorders				
Asthma	8	(44.4)	12	(54.5)
Chronic obstructive pulmonary disease			1	(4.5)
Dysphonia			1	(4.5)
Rhinitis allergic			1	(4.5)
Skin and subcutaneous tissue disorders				
Photosensitivity reaction	1	(5.6)	1	(4.5)
Acne			1	(4.5)
Alopecia areata			1	(4.5)
Rosacea			1	(4.5)
Social circumstances				
Menopause			1	(4.5)
Surgical and medical procedures				
Cardiac pacemaker insertion			1	(4.5)
Vascular disorders				
Hypertension	7	(38.9)	6	(27.3)
Peripheral venous disease	1	(5.6)	3	(13.6)
Spider vein			1	(4.5)
Varicose vein			1	(4.5)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.16.102.4.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Analysis set				
N	119		116	
Blood and lymphatic system disorders				
Eosinophilia			1	(0.9)
Iron deficiency anaemia			1	(0.9)
Lymphadenopathy			1	(0.9)
Normochromic normocytic anaemia	1	(0.8)		
Thrombocytopenia	1	(0.8)		
Cardiac disorders				
Bundle branch block right	3	(2.5)		
Sinus bradycardia	1	(0.8)	2	(1.7)
Bradycardia			1	(0.9)
Bundle branch block left			1	(0.9)
Congestive cardiomyopathy			1	(0.9)
Mitral valve incompetence			1	(0.9)
Tachycardia			1	(0.9)
Atrial fibrillation	1	(0.8)		
Atrial flutter	1	(0.8)		
Atrioventricular block	1	(0.8)		
Myocardial infarction	1	(0.8)		
Myocardial ischaemia	1	(0.8)		
Congenital, familial and genetic disorders				
Benign familial haematuria	1	(0.8)		
Congenital anomaly	1	(0.8)		
Congenital cystic kidney disease	1	(0.8)		
Cytogenetic abnormality	1	(0.8)		
Gilbert's syndrome	1	(0.8)		
Sickle cell anaemia	1	(0.8)		
Ear and labyrinth disorders				
Deafness neurosensory	1	(0.8)		
Tinnitus	1	(0.8)		
Endocrine disorders				
Hypothyroidism	2	(1.7)	7	(6.0)
Autoimmune thyroiditis	3	(2.5)		
Goitre			1	(0.9)
Hyperprolactinaemia			1	(0.9)
Thyroiditis			1	(0.9)
Thyroid mass	1	(0.8)		
Eye disorders				
Conjunctivitis allergic	33	(27.7)	33	(28.4)
Atopic keratoconjunctivitis	9	(7.6)	1	(0.9)
Keratoconus	3	(2.5)		
Myopia			2	(1.7)
Dry eye	2	(1.7)		
Blepharitis			1	(0.9)
Cataract			1	(0.9)
Glaucoma	1	(0.8)	1	(0.9)
Keratitis			1	(0.9)
Photophobia			1	(0.9)
Astigmatism	1	(0.8)		
Gastrointestinal disorders				
Gastrooesophageal reflux disease	3	(2.5)	2	(1.7)
Oesophagitis			2	(1.7)
Irritable bowel syndrome	2	(1.7)	1	(0.9)
Coeliac disease	1	(0.8)	1	(0.9)
Colitis ulcerative			1	(0.9)
Dyspepsia			1	(0.9)

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Table 1.16.102.4.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Gastrointestinal disorders				
Gastric ulcer			1	(0.9)
Haemorrhoids	1	(0.8)	1	(0.9)
Hiatus hernia	1	(0.8)	1	(0.9)
Barrett's oesophagus	1	(0.8)		
Chronic gastritis	1	(0.8)		
Crohn's disease	1	(0.8)		
Gastritis	1	(0.8)		
General disorders and administration site conditions				
Xerosis	1	(0.8)	4	(3.4)
Dysplasia	1	(0.8)		
Hernia	1	(0.8)		
Oedema peripheral	1	(0.8)		
Hepatobiliary disorders				
Hepatic steatosis			1	(0.9)
Immune system disorders				
Seasonal allergy	60	(50.4)	63	(54.3)
Food allergy	45	(37.8)	43	(37.1)
Allergy to animal	14	(11.8)	7	(6.0)
Mite allergy	13	(10.9)	11	(9.5)
Multiple allergies	8	(6.7)	11	(9.5)
Drug hypersensitivity	8	(6.7)	10	(8.6)
Allergy to plants	2	(1.7)	4	(3.4)
Rubber sensitivity	1	(0.8)	4	(3.4)
Allergy to metals	1	(0.8)	3	(2.6)
Allergy to chemicals	1	(0.8)	2	(1.7)
Dust allergy	1	(0.8)	2	(1.7)
Hypersensitivity	2	(1.7)	2	(1.7)
Milk allergy	1	(0.8)	2	(1.7)
Iodine allergy			1	(0.9)
Mycotic allergy	1	(0.8)	1	(0.9)
Oral allergy syndrome			1	(0.9)
Perfume sensitivity			1	(0.9)
Flour sensitivity	1	(0.8)		
Infections and infestations				
Herpes simplex	9	(7.6)	11	(9.5)
Oral herpes	1	(0.8)	2	(1.7)
Rhinitis			2	(1.7)
Sinusitis	2	(1.7)	1	(0.9)
Ear infection			1	(0.9)
Papilloma viral infection			1	(0.9)
Skin candida			1	(0.9)
Conjunctivitis	1	(0.8)		
Onychomycosis	1	(0.8)		
Injury, poisoning and procedural complications				
Scar			2	(1.7)
Ligament sprain			1	(0.9)
Meniscus injury			1	(0.9)
Deafness traumatic	1	(0.8)		
Investigations				
Blood immunoglobulin E increased	1	(0.8)	1	(0.9)
Blood uric acid increased			1	(0.9)
Gamma-glutamyltransferase increased	1	(0.8)	1	(0.9)
Aspartate aminotransferase increased	1	(0.8)		
Lymph node palpable	1	(0.8)		
Mean cell volume increased	1	(0.8)		
Neutrophil count increased	1	(0.8)		
Vitamin B12 decreased	1	(0.8)		

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Table 1.16.102.4.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Rest of World		
Investigations		
White blood cell count increased	1 (0.8)	
Metabolism and nutrition disorders		
Hypercholesterolaemia	2 (1.7)	5 (4.3)
Gluten sensitivity	3 (2.5)	
Diabetes mellitus		2 (1.7)
Hyperuricaemia		2 (1.7)
Vitamin D deficiency	2 (1.7)	2 (1.7)
Dyslipidaemia	2 (1.7)	1 (0.9)
Lactose intolerance	2 (1.7)	
Histamine intolerance		1 (0.9)
Hyperinsulinism		1 (0.9)
Hypertriglyceridaemia		1 (0.9)
Iron deficiency		1 (0.9)
Obesity	1 (0.8)	1 (0.9)
Overweight		1 (0.9)
Purine metabolism disorder		1 (0.9)
Glucose tolerance impaired	1 (0.8)	
Gout	1 (0.8)	
Hyperlipidaemia	1 (0.8)	
Mineral deficiency	1 (0.8)	
Musculoskeletal and connective tissue disorders		
Back pain	1 (0.8)	4 (3.4)
Intervertebral disc protrusion	1 (0.8)	2 (1.7)
Arthralgia	2 (1.7)	
Myalgia	2 (1.7)	
Osteopenia	2 (1.7)	
Ankylosing spondylitis		1 (0.9)
Fibromyalgia		1 (0.9)
Foot deformity		1 (0.9)
Lumbar spinal stenosis		1 (0.9)
Muscle spasms		1 (0.9)
Osteoarthritis	1 (0.8)	1 (0.9)
Osteoporosis		1 (0.9)
Spinal pain		1 (0.9)
Growth retardation	1 (0.8)	
Intervertebral disc disorder	1 (0.8)	
Joint range of motion decreased	1 (0.8)	
Osteochondrosis	1 (0.8)	
Plica syndrome	1 (0.8)	
Spinal osteoarthritis	1 (0.8)	
Temporomandibular joint syndrome	1 (0.8)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Blepharal papilloma		1 (0.9)
Haemangioma of liver		1 (0.9)
Melanocytic naevus		1 (0.9)
Skin papilloma		1 (0.9)
Haemangioma	1 (0.8)	
Nervous system disorders		
Migraine	5 (4.2)	6 (5.2)
Headache	4 (3.4)	5 (4.3)
Dysaesthesia	1 (0.8)	
Epilepsy	1 (0.8)	
Hydrocephalus	1 (0.8)	
Migraine with aura	1 (0.8)	
Multiple sclerosis	1 (0.8)	
Narcolepsy	1 (0.8)	
Paralysis	1 (0.8)	
Restless legs syndrome	1 (0.8)	
Psychiatric disorders		
Anxiety	1 (0.8)	

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Table 1.16.102.4.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Psychiatric disorders				
Anxiety			5	(4.3)
Depressed mood	1	(0.8)	2	(1.7)
Depression	2	(1.7)	2	(1.7)
Insomnia	2	(1.7)	1	(0.9)
Affective disorder			1	(0.9)
Sleep disorder			1	(0.9)
Stress			1	(0.9)
Eating disorder	1	(0.8)		
Fear of injection	1	(0.8)		
Nervousness	1	(0.8)		
Renal and urinary disorders				
Proteinuria	3	(2.5)		
Haematuria	2	(1.7)		
Chronic kidney disease			1	(0.9)
IgA nephropathy			1	(0.9)
Nephrolithiasis			1	(0.9)
Renal failure			1	(0.9)
Renal cyst	1	(0.8)		
Renal disorder	1	(0.8)		
Renal vein compression	1	(0.8)		
Reproductive system and breast disorders				
Benign prostatic hyperplasia	1	(0.8)	1	(0.9)
Dysmenorrhoea	1	(0.8)	1	(0.9)
Gynaecomastia			1	(0.9)
Ovarian cyst			1	(0.9)
Testicular cyst			1	(0.9)
Erectile dysfunction	1	(0.8)		
Polycystic ovaries	1	(0.8)		
Premenstrual syndrome	1	(0.8)		
Respiratory, thoracic and mediastinal disorders				
Asthma	66	(55.5)	50	(43.1)
Rhinitis allergic	20	(16.8)	8	(6.9)
Nasal septum deviation	2	(1.7)	2	(1.7)
Bronchiectasis			1	(0.9)
Bronchitis chronic			1	(0.9)
Chronic obstructive pulmonary disease			1	(0.9)
Nasal turbinate hypertrophy			1	(0.9)
Sleep apnoea syndrome			1	(0.9)
Bronchial hyperreactivity	1	(0.8)		
Nasal polyps	1	(0.8)		
Sinus disorder	1	(0.8)		
Skin and subcutaneous tissue disorders				
Alopecia areata	3	(2.5)		
Alopecia	2	(1.7)		
Acne			1	(0.9)
Androgenetic alopecia			1	(0.9)
Dermatitis contact	1	(0.8)	1	(0.9)
Urticaria	1	(0.8)	1	(0.9)
Vitiligo	1	(0.8)	1	(0.9)
Psoriasis	1	(0.8)		
Skin sensitisation	1	(0.8)		
Social circumstances				
Menopause			1	(0.9)
Postmenopause	1	(0.8)		
Surgical and medical procedures				
Cardiac resynchronisation therapy			1	(0.9)
Contraception			1	(0.9)
Intra-uterine contraceptive device			1	(0.9)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.16.102.4.1: Total, Rest of World, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Surgical and medical procedures				
Knee operation			1	(0.9)
Female sterilisation	1	(0.8)		
Gastric bypass	1	(0.8)		
Lip lesion excision	1	(0.8)		
Maxillofacial operation	1	(0.8)		
Nasal septal operation	1	(0.8)		
Sterilisation	1	(0.8)		
Thyroid nodule removal	1	(0.8)		
Thyroidectomy	1	(0.8)		
Vascular disorders				
Hypertension	18	(15.1)	17	(14.7)
Peripheral venous disease	1	(0.8)		
Varicose vein	1	(0.8)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.16.103.4.1: Total, Germany, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Germany				
Analysis set				
N	18		22	
Eye disorders				
Cataract	1	(5.6)	1	(4.5)
Gastrointestinal disorders				
Inguinal hernia			1	(4.5)
General disorders and administration site conditions				
Hernia			1	(4.5)
Immune system disorders				
Hypersensitivity	1	(5.6)		
Oral allergy syndrome	1	(5.6)		
Infections and infestations				
Appendicitis	1	(5.6)		
Herpes simplex	1	(5.6)	1	(4.5)
Herpes zoster			1	(4.5)
Injury, poisoning and procedural complications				
Joint injury	1	(5.6)		
Ligament rupture	1	(5.6)		
Upper limb fracture	1	(5.6)	1	(4.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Anogenital warts	1	(5.6)		
Basal cell carcinoma	1	(5.6)		
Benign pancreatic neoplasm	1	(5.6)		
Prostate cancer	1	(5.6)		
Skin papilloma	1	(5.6)		
Squamous cell carcinoma of skin	1	(5.6)		
Psychiatric disorders				
Depression			3	(13.6)
Drug use disorder	1	(5.6)		
Reproductive system and breast disorders				
Breast cyst	1	(5.6)		
Sexual dysfunction			1	(4.5)
Respiratory, thoracic and mediastinal disorders				
Asthma			1	(4.5)
Pneumothorax			1	(4.5)
Skin and subcutaneous tissue disorders				
Dermatitis contact	1	(5.6)		
Rosacea	1	(5.6)		
Alopecia			1	(4.5)
Surgical and medical procedures				
Tonsillectomy			3	(13.6)
Appendicectomy			2	(9.1)
Hysterectomy	1	(5.6)	2	(9.1)
Caesarean section	1	(5.6)		
Prophylaxis	1	(5.6)		
Strabismus correction	1	(5.6)		
Bunion operation			1	(4.5)
Carpal tunnel decompression			1	(4.5)
Cataract operation			1	(4.5)
Cervical conisation			1	(4.5)
Female sterilisation			1	(4.5)
Fracture treatment			1	(4.5)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.16.103.4.1: Total, Germany, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Germany				
Surgical and medical procedures				
Knee operation			1	(4.5)
Meniscus operation			1	(4.5)
Nasal polypectomy			1	(4.5)
Oophorectomy			1	(4.5)
Pleurodesis			1	(4.5)
Thyroidectomy			1	(4.5)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.16.103.4.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Analysis set				
N	119		116	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	2	(1.7)		
Iron deficiency anaemia	1	(0.8)		
Neutropenia	1	(0.8)		
Cardiac disorders				
Myocardial ischaemia			1	(0.9)
Pericarditis			1	(0.9)
Bundle branch block left	1	(0.8)		
Cardiac failure	1	(0.8)		
Congenital, familial and genetic disorders				
Phimosis			2	(1.7)
Endocrine disorders				
Thyroid mass			1	(0.9)
Basedow's disease	1	(0.8)		
Goitre	1	(0.8)		
Eye disorders				
Conjunctivitis allergic	4	(3.4)	3	(2.6)
Cataract			2	(1.7)
Atopic keratoconjunctivitis			1	(0.9)
Keratitis	1	(0.8)	1	(0.9)
Keratoconus			1	(0.9)
Retinal detachment			1	(0.9)
Corneal oedema	1	(0.8)		
Lacrimation increased	1	(0.8)		
Gastrointestinal disorders				
Haemorrhoids			1	(0.9)
Hiatus hernia			1	(0.9)
Intestinal obstruction			1	(0.9)
Proctitis			1	(0.9)
Gastrooesophageal reflux disease	1	(0.8)		
Pancreatitis acute	1	(0.8)		
General disorders and administration site conditions				
Hypothermia			1	(0.9)
Dysplasia	1	(0.8)		
Immune system disorders				
Seasonal allergy			2	(1.7)
Mite allergy			1	(0.9)
Corneal graft rejection	1	(0.8)		
Infections and infestations				
Impetigo	10	(8.4)	5	(4.3)
Herpes simplex	2	(1.7)	6	(5.2)
Eczema herpeticum	6	(5.0)	2	(1.7)
Herpes zoster	6	(5.0)	5	(4.3)
Erysipelas			2	(1.7)
Meningitis viral			2	(1.7)
Varicella	2	(1.7)	2	(1.7)
Infectious mononucleosis	2	(1.7)		
Meningitis	2	(1.7)		
Ophthalmic herpes simplex	2	(1.7)		
Oral herpes	2	(1.7)		
Bacterial infection			1	(0.9)
Cellulitis			1	(0.9)
Conjunctivitis	1	(0.8)		

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Table 1.16.103.4.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Rest of World		
Infections and infestations		
Conjunctivitis		1 (0.9)
Groin abscess		1 (0.9)
Herpes ophthalmic		1 (0.9)
Infection parasitic		1 (0.9)
Myringitis		1 (0.9)
Otitis media		1 (0.9)
Post procedural infection		1 (0.9)
Staphylococcal skin infection		1 (0.9)
Vaginal infection		1 (0.9)
Vulvovaginal candidiasis		1 (0.9)
Appendicitis	1 (0.8)	
Dermatitis infected	1 (0.8)	
Enterobiasis	1 (0.8)	
Epiglottitis	1 (0.8)	
Furuncle	1 (0.8)	
Helicobacter gastritis	1 (0.8)	
Mumps	1 (0.8)	
Otitis externa	1 (0.8)	
Pilonidal cyst	1 (0.8)	
Pneumonia	1 (0.8)	
Postoperative wound infection	1 (0.8)	
Pyelonephritis	1 (0.8)	
Rhinitis	1 (0.8)	
Skin bacterial infection	1 (0.8)	
Staphylococcal infection	1 (0.8)	
Tinea cruris	1 (0.8)	
Tuberculosis	1 (0.8)	
Upper respiratory tract infection	1 (0.8)	
Urinary tract infection	1 (0.8)	
Injury, poisoning and procedural complications		
Ankle fracture		1 (0.9)
Comminuted fracture		1 (0.9)
Facial bones fracture	1 (0.8)	1 (0.9)
Foot fracture		1 (0.9)
Ligament sprain		1 (0.9)
Limb fracture		1 (0.9)
Post-traumatic neck syndrome		1 (0.9)
Spinal fracture		1 (0.9)
Tibia fracture		1 (0.9)
Upper limb fracture	1 (0.8)	1 (0.9)
Wrist fracture		1 (0.9)
Chillblains	1 (0.8)	
Clavicle fracture	1 (0.8)	
Femur fracture	1 (0.8)	
Hand fracture	1 (0.8)	
Humerus fracture	1 (0.8)	
Joint dislocation	1 (0.8)	
Joint injury	1 (0.8)	
Ligament injury	1 (0.8)	
Meniscus injury	1 (0.8)	
Multiple fractures	1 (0.8)	
Wound secretion	1 (0.8)	
Investigations		
Arthroscopy	1 (0.8)	
Biopsy breast	1 (0.8)	
Biopsy lymph gland	1 (0.8)	
Skin test	1 (0.8)	
Metabolism and nutrition disorders		
Lactose intolerance		1 (0.9)
Hypoproteinaemia	1 (0.8)	
Starvation	1 (0.8)	

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Table 1.16.103.4.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Rest of World				
Musculoskeletal and connective tissue disorders				
Foot deformity			1	(0.9)
Joint contracture			1	(0.9)
Lumbar spinal stenosis			1	(0.9)
Bursitis	1	(0.8)		
Intervertebral disc protrusion	1	(0.8)		
Osteoarthritis	1	(0.8)		
Osteochondrosis	1	(0.8)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Bladder transitional cell carcinoma			1	(0.9)
Hodgkin's disease			1	(0.9)
Renal cancer			1	(0.9)
Sweat gland tumour			1	(0.9)
Testis cancer			1	(0.9)
Acanthoma	1	(0.8)		
Anogenital warts	1	(0.8)		
Bowen's disease	1	(0.8)		
Breast cancer	1	(0.8)		
Melanocytic naevus	1	(0.8)		
Papilloma	1	(0.8)		
Nervous system disorders				
Epilepsy	2	(1.7)		
Cerebral ischaemia			1	(0.9)
Migraine	1	(0.8)	1	(0.9)
Paraesthesia			1	(0.9)
Seizure			1	(0.9)
Restless legs syndrome	1	(0.8)		
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous	1	(0.8)		
HELLP syndrome	1	(0.8)		
Psychiatric disorders				
Depression	2	(1.7)	2	(1.7)
Adjustment disorder with depressed mood			1	(0.9)
Anxiety			1	(0.9)
Panic attack			1	(0.9)
Alcoholism	1	(0.8)		
Insomnia	1	(0.8)		
Mood altered	1	(0.8)		
Stress	1	(0.8)		
Renal and urinary disorders				
Nephrolithiasis	2	(1.7)		
Renal colic			1	(0.9)
Ureterolithiasis			1	(0.9)
Acute kidney injury	1	(0.8)		
Hydronephrosis	1	(0.8)		
Reproductive system and breast disorders				
Ovarian cyst			1	(0.9)
Varicocele			1	(0.9)
Acquired phimosis	1	(0.8)		
Polycystic ovaries	1	(0.8)		
Respiratory, thoracic and mediastinal disorders				
Asthma	2	(1.7)	7	(6.0)
Rhinitis allergic	2	(1.7)	1	(0.9)
Bronchospasm			1	(0.9)
Pulmonary embolism			1	(0.9)
Maxillary sinus pseudocyst	1	(0.8)		
Skin and subcutaneous tissue disorders				
Acne	1	(0.8)		

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Table 1.16.103.4.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Rest of World		
Skin and subcutaneous tissue disorders		
Acne		1 (0.9)
Alopecia		1 (0.9)
Alopecia areata		1 (0.9)
Angioedema		1 (0.9)
Dermatitis contact	1 (0.8)	1 (0.9)
Hidradenitis		1 (0.9)
Ingrowing nail		1 (0.9)
Purpura		1 (0.9)
Seborrhoeic dermatitis		1 (0.9)
Acne conglobata	1 (0.8)	
Dermal cyst	1 (0.8)	
Dermatitis exfoliative	1 (0.8)	
Surgical and medical procedures		
Tonsillectomy	1 (0.8)	6 (5.2)
Appendicectomy	4 (3.4)	1 (0.9)
Caesarean section	2 (1.7)	3 (2.6)
Adenoidectomy	3 (2.5)	2 (1.7)
Cholecystectomy	3 (2.5)	1 (0.9)
Ligament operation	3 (2.5)	2 (1.7)
Abscess drainage		2 (1.7)
Arthrodesis		2 (1.7)
Cataract operation		2 (1.7)
Cyst removal	1 (0.8)	2 (1.7)
Nephrectomy		2 (1.7)
Turbinoplasty	1 (0.8)	2 (1.7)
UV light therapy		2 (1.7)
Immunisation	2 (1.7)	
Nasal septal operation	2 (1.7)	1 (0.9)
Adrenalectomy		1 (0.9)
Amygdalotomy		1 (0.9)
Circumcision		1 (0.9)
Eye operation		1 (0.9)
Female genital operation		1 (0.9)
Hepatitis B immunisation		1 (0.9)
Hospitalisation		1 (0.9)
Hysterectomy	1 (0.8)	1 (0.9)
Inguinal hernia repair	1 (0.8)	1 (0.9)
Knee operation		1 (0.9)
Lip lesion excision		1 (0.9)
Meniscus removal		1 (0.9)
Myopia correction		1 (0.9)
Skin neoplasm excision		1 (0.9)
Tooth extraction	1 (0.8)	1 (0.9)
Wisdom teeth removal	1 (0.8)	1 (0.9)
Benign tumour excision	1 (0.8)	
Cardiac ablation	1 (0.8)	
Carpal tunnel decompression	1 (0.8)	
Endometrial ablation	1 (0.8)	
Eye laser surgery	1 (0.8)	
Finger amputation	1 (0.8)	
Hernia repair	1 (0.8)	
In vitro fertilisation	1 (0.8)	
Jaw operation	1 (0.8)	
Keratoplasty	1 (0.8)	
Large intestinal polypectomy	1 (0.8)	
Meniscus operation	1 (0.8)	
Myringotomy	1 (0.8)	
Oral surgery	1 (0.8)	
Ovarian cystectomy	1 (0.8)	
Pneumococcal immunisation	1 (0.8)	
Polypectomy	1 (0.8)	
Shoulder operation	1 (0.8)	
Sinus operation	1 (0.8)	

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Table 1.16.103.4.1: Total, Rest of World, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Rest of World		
Surgical and medical procedures		
Small intestinal resection	1 (0.8)	
Spinal operation	1 (0.8)	
Stent placement	1 (0.8)	
Tumour excision	1 (0.8)	
Varicose vein operation	1 (0.8)	
Ventriculo-peritoneal shunt	1 (0.8)	
Vascular disorders		
Infarction		1 (0.9)
Thrombophlebitis	1 (0.8)	1 (0.9)
Hypertension	1 (0.8)	

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.16.104.4.1: Total, Germany, Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	22 (100.0)	18 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	7 (31.8)	8 (44.4)
More than 3	5 (22.7)	4 (22.2)
Never	10 (45.5)	8 (44.4)
Past	4 (18.2)	2 (11.1)
More than 3	3 (13.6)	
Unknown	1 (4.5)	
ASTHMA		
Current	12 (54.5)	8 (44.4)
Never	9 (40.9)	10 (55.6)
Past	1 (4.5)	
ATOPIC KERATOCONJUNCTIVITIS		
Never	21 (95.5)	18 (100.0)
Unknown	1 (4.5)	
ECZEMA HERPETICUM		
Never	20 (90.9)	18 (100.0)
Past	1 (4.5)	
More than 3	1 (4.5)	
Unknown	1 (4.5)	
FOOD ALLERGY		
Current	7 (31.8)	6 (33.3)
Never	14 (63.6)	10 (55.6)
Past		1 (5.6)
Unknown	1 (4.5)	1 (5.6)
HAY FEVER		
Current	12 (54.5)	10 (55.6)
Never	7 (31.8)	7 (38.9)
Past	2 (9.1)	
Unknown	1 (4.5)	1 (5.6)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.16.104.4.1: Total, Rest of World, Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	116 (100.0)	119 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	34 (29.3)	33 (27.7)
More than 3	19 (16.4)	25 (21.0)
Never	62 (53.4)	66 (55.5)
Past	18 (15.5)	19 (16.0)
More than 3	9 (7.8)	12 (10.1)
Unknown	2 (1.7)	1 (0.8)
ASTHMA		
Current	50 (43.1)	66 (55.5)
Never	54 (46.6)	48 (40.3)
Past	12 (10.3)	5 (4.2)
ATOPIC KERATOCONJUNCTIVITIS		
Current		9 (7.6)
More than 3		5 (4.2)
Never	110 (94.8)	99 (83.2)
Past	4 (3.4)	9 (7.6)
More than 3		3 (2.5)
Unknown	2 (1.7)	2 (1.7)
ECZEMA HERPETICUM		
Never	101 (87.1)	100 (84.0)
Past	13 (11.2)	15 (12.6)
More than 3	3 (2.6)	3 (2.5)
Unknown	2 (1.7)	4 (3.4)
FOOD ALLERGY		
Current	49 (42.2)	49 (41.2)
Never	64 (55.2)	67 (56.3)
Past	2 (1.7)	1 (0.8)
Unknown	1 (0.9)	2 (1.7)
HAY FEVER		
Current	64 (55.2)	67 (56.3)
Never	44 (37.9)	45 (37.8)
Past	8 (6.9)	5 (4.2)
Unknown		2 (1.7)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.16.105.4.1: Total, Germany, Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	22 (100.0)	18 (100.0)
ALOPECIA		
Current	1 (4.5)	
Never	20 (90.9)	18 (100.0)
Past	1 (4.5)	
CELLULITIS		
Never	21 (95.5)	18 (100.0)
Unknown	1 (4.5)	
HERPES SIMPLEX		
Current	2 (9.1)	2 (11.1)
More than 3	2 (9.1)	1 (5.6)
Never	14 (63.6)	13 (72.2)
Past	5 (22.7)	2 (11.1)
More than 3	2 (9.1)	
Unknown	1 (4.5)	1 (5.6)
IMPETIGO		
Never	22 (100.0)	17 (94.4)
Past		1 (5.6)
OTHER SKIN INFECTIONS		
Never	20 (90.9)	18 (100.0)
Unknown	2 (9.1)	
VITILIGO		
Never	22 (100.0)	18 (100.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.16.105.4.1: Total, Rest of World, Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	116 (100.0)	119 (100.0)
ALOPECIA		
Current	1 (0.9)	5 (4.2)
Never	113 (97.4)	112 (94.1)
Past	1 (0.9)	1 (0.8)
Unknown	1 (0.9)	1 (0.8)
CELLULITIS		
Never	109 (94.0)	112 (94.1)
Past	3 (2.6)	7 (5.9)
Unknown	4 (3.4)	
HERPES SIMPLEX		
Current	12 (10.3)	10 (8.4)
More than 3	5 (4.3)	7 (5.9)
Never	78 (67.2)	76 (63.9)
Past	23 (19.8)	33 (27.7)
More than 3	10 (8.6)	23 (19.3)
Unknown	3 (2.6)	
IMPETIGO		
Never	86 (74.1)	82 (68.9)
Past	27 (23.3)	35 (29.4)
More than 3	8 (6.9)	13 (10.9)
Unknown	3 (2.6)	2 (1.7)
OTHER SKIN INFECTIONS		
Never	97 (83.6)	99 (83.2)
Past	12 (10.3)	15 (12.6)
Unknown	7 (6.0)	5 (4.2)
VITILIGO		
Current	1 (0.9)	1 (0.8)
Never	113 (97.4)	118 (99.2)
Past	1 (0.9)	
Unknown	1 (0.9)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.16.107.4.1: Total, Germany, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	22 (100.0)	18 (100.0)
Antibiotics		
Yes	3 (13.6)	7 (38.9)
No	17 (77.3)	11 (61.1)
Unknown	2 (9.1)	
Azathioprine		
Yes		2 (11.1)
More than 12 weeks?		
Yes		1 (5.6)
Unknown		1 (5.6)
Reason for discontinuation		
Inadequate efficacy		2 (11.1)
No	22 (100.0)	16 (88.9)
Reason for not using		
Contraindications	1 (4.5)	1 (5.6)
Risk of side effects	9 (40.9)	7 (38.9)
Other	12 (54.5)	8 (44.4)
Cyclosporine		
Yes	13 (59.1)	12 (66.7)
More than 12 weeks?		
Yes	8 (36.4)	7 (38.9)
No	5 (22.7)	5 (27.8)
Reason for discontinuation		
Inadequate efficacy	6 (27.3)	6 (33.3)
Side effects	7 (31.8)	6 (33.3)
No	9 (40.9)	6 (33.3)
Reason for not using		
Contraindications	7 (31.8)	5 (27.8)
Risk of side effects	1 (4.5)	1 (5.6)
Other	1 (4.5)	
Methotrexate		
Yes		1 (5.6)
More than 12 weeks?		
Yes		1 (5.6)
Reason for discontinuation		
Inadequate efficacy		1 (5.6)
No	22 (100.0)	17 (94.4)
Reason for not using		
Contraindications	2 (9.1)	
Risk of side effects	8 (36.4)	9 (50.0)
Other	12 (54.5)	8 (44.4)
Monoclonal antibody/Dupilumab		
Yes	2 (9.1)	4 (22.2)
No	20 (90.9)	14 (77.8)
Mycophenolate		
No	22 (100.0)	18 (100.0)
Reason for not using		
Contraindications	1 (4.5)	1 (5.6)
Risk of side effects	10 (45.5)	8 (44.4)
Other	11 (50.0)	9 (50.0)
Other immunosuppressant		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.16.107.4.1: Total, Germany, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	3 (13.6)	
No	19 (86.4)	18 (100.0)
Phototherapy		
Yes	14 (63.6)	12 (66.7)
No	8 (36.4)	6 (33.3)
Systemic steroids		
Yes	12 (54.5)	10 (55.6)
No	9 (40.9)	7 (38.9)
Unknown	1 (4.5)	1 (5.6)
Topical calcineurin inhibitor		
Yes	14 (63.6)	13 (72.2)
No	7 (31.8)	5 (27.8)
Unknown	1 (4.5)	
Topical corticosteroids		
Yes	22 (100.0)	18 (100.0)
Highest potency		
High	16 (72.7)	11 (61.1)
Moderate	2 (9.1)	6 (33.3)
Ultra high	2 (9.1)	1 (5.6)
Unknown	2 (9.1)	
Wet wraps		
Yes	7 (31.8)	7 (38.9)
No	14 (63.6)	11 (61.1)
Unknown	1 (4.5)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.16.107.4.1: Total, Rest of World, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	116 (100.0)	119 (100.0)
Antibiotics		
Yes	52 (44.8)	59 (49.6)
No	59 (50.9)	51 (42.9)
Unknown	5 (4.3)	9 (7.6)
Azathioprine		
Yes	18 (15.5)	16 (13.4)
More than 12 weeks?		
Yes	13 (11.2)	11 (9.2)
No	4 (3.4)	3 (2.5)
Unknown	1 (0.9)	2 (1.7)
Reason for discontinuation		
Inadequate efficacy	12 (10.3)	12 (10.1)
Other	1 (0.9)	2 (1.7)
Side effects	5 (4.3)	2 (1.7)
No	92 (79.3)	100 (84.0)
Reason for not using		
Contraindications	4 (3.4)	9 (7.6)
Risk of side effects	35 (30.2)	26 (21.8)
Other	53 (45.7)	65 (54.6)
Unknown	6 (5.2)	3 (2.5)
Cyclosporine		
Yes	91 (78.4)	90 (75.6)
More than 12 weeks?		
Yes	62 (53.4)	64 (53.8)
No	29 (25.0)	25 (21.0)
Unknown		1 (0.8)
Reason for discontinuation		
Treatment duration >	5 (4.3)	7 (5.9)
Inadequate efficacy	45 (38.8)	37 (31.1)
Other	7 (6.0)	7 (5.9)
Side effects	34 (29.3)	39 (32.8)
No	25 (21.6)	29 (24.4)
Reason for not using		
Contraindications	21 (18.1)	19 (16.0)
Risk of side effects	3 (2.6)	3 (2.5)
Other	1 (0.9)	7 (5.9)
Methotrexate		
Yes	23 (19.8)	25 (21.0)
More than 12 weeks?		
Yes	15 (12.9)	17 (14.3)
No	8 (6.9)	7 (5.9)
Unknown		1 (0.8)
Reason for discontinuation		
Inadequate efficacy	15 (12.9)	17 (14.3)
Other	1 (0.9)	2 (1.7)
Side effects	7 (6.0)	6 (5.0)
No	91 (78.4)	92 (77.3)
Reason for not using		
Contraindications	9 (7.8)	12 (10.1)
Risk of side effects	31 (26.7)	23 (19.3)
Other	51 (44.0)	57 (47.9)
Unknown	2 (1.7)	2 (1.7)
Monoclonal antibody/Dupilumab		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.16.107.4.1: Total, Rest of World, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	7 (6.0)	8 (6.7)
No	107 (92.2)	110 (92.4)
Unknown	2 (1.7)	1 (0.8)
Mycophenolate		
Yes	3 (2.6)	5 (4.2)
More than 12 weeks?		
Yes	3 (2.6)	1 (0.8)
No		4 (3.4)
Reason for discontinuation		
Inadequate efficacy	3 (2.6)	3 (2.5)
Side effects		2 (1.7)
No	105 (90.5)	111 (93.3)
Reason for not using		
Contraindications	3 (2.6)	7 (5.9)
Risk of side effects	35 (30.2)	26 (21.8)
Other	66 (56.9)	78 (65.5)
Unknown	8 (6.9)	3 (2.5)
Other immunosuppressant		
Yes	13 (11.2)	12 (10.1)
No	101 (87.1)	105 (88.2)
Unknown	2 (1.7)	2 (1.7)
Phototherapy		
Yes	65 (56.0)	72 (60.5)
No	50 (43.1)	47 (39.5)
Unknown	1 (0.9)	
Systemic steroids		
Yes	85 (73.3)	81 (68.1)
No	27 (23.3)	32 (26.9)
Unknown	4 (3.4)	6 (5.0)
Topical calcineurin inhibitor		
Yes	78 (67.2)	82 (68.9)
No	30 (25.9)	35 (29.4)
Unknown	8 (6.9)	2 (1.7)
Topical corticosteroids		
Yes	116 (100.0)	118 (99.2)
Highest potency		
High	60 (51.7)	43 (36.1)
Low		1 (0.8)
Moderate	8 (6.9)	9 (7.6)
Ultra high	41 (35.3)	62 (52.1)
Unknown	7 (6.0)	3 (2.5)
No		1 (0.8)
Wet wraps		
Yes	18 (15.5)	12 (10.1)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.16.107.4.1: Total, Rest of World, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	90 (77.6)	103 (86.6)
Unknown	8 (6.9)	4 (3.4)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.16.325.4.1: Total, Region, EASI 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	88 (63.8)	15.3 (3.72;26.79)	1.3 (1.06; 1.62)	1.9 (1.16; 3.05)	0.0104	0.7757
Placebo + TCS	137	67 (48.9)					
Germany							
Tralokinumab Q2W + TCS	22	14 (63.6)	18.5 (-11.0;48.04)	1.4 (0.79; 2.51)	2.3 (0.59; 9.03)	0.2422	
Placebo + TCS	18	8 (44.4)					
Rest of World							
Tralokinumab Q2W + TCS	116	74 (63.8)	15.0 (2.63;27.41)	1.3 (1.04; 1.63)	1.9 (1.10; 3.20)	0.0185	
Placebo + TCS	119	59 (49.6)					

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 Prior CSA use and baseline IGA.

Table 1.16.326.4.1: Total, Region, EASI 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	57 (41.3)	14.2 (3.21;25.12)	1.5 (1.09; 2.10)	1.9 (1.15; 3.21)	0.0123	0.5190
Placebo + TCS	137	38 (27.7)					
Germany							
Tralokinumab Q2W + TCS	22	7 (31.8)	4.4 (-24.1;32.89)	1.2 (0.46; 2.86)	1.2 (0.31; 5.02)	0.7694	
Placebo + TCS	18	5 (27.8)					
Rest of World							
Tralokinumab Q2W + TCS	116	50 (43.1)	16.5 (4.54;28.45)	1.6 (1.13; 2.27)	2.1 (1.21; 3.66)	0.0074	
Placebo + TCS	119	33 (27.7)					

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 Prior CSA use and baseline IGA.

Table 1.16.329.4.1: Total, Region, SCORAD 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	40 (29.0)	16.9 (7.55;26.16)	2.4 (1.42; 3.96)	3.0 (1.58; 5.62)	0.0006	0.1497
Placebo + TCS	137	17 (12.4)					
Germany							
Tralokinumab Q2W + TCS	22	5 (22.7)	-0.2 (-26.8;26.46)	1.0 (0.32; 3.06)	1.0 (0.22; 4.40)	0.9899	
Placebo + TCS	18	4 (22.2)					
Rest of World							
Tralokinumab Q2W + TCS	116	35 (30.2)	19.8 (9.71;29.85)	2.8 (1.58; 5.02)	3.6 (1.80; 7.34)	0.0002	
Placebo + TCS	119	13 (10.9)					

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 Prior CSA use and baseline IGA.

Table 1.16.330.4.1: Total, Region, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	134	62 (46.3)	9.7 (-1.99;21.41)	1.3 (0.95; 1.69)	1.5 (0.92; 2.44)	0.1068	0.8776
Placebo + TCS	135	49 (36.3)					
Germany							
Tralokinumab Q2W + TCS	22	9 (40.9)	9.0 (-21.7;39.63)	1.3 (0.54; 3.05)	1.5 (0.40; 5.31)	0.5787	
Placebo + TCS	18	6 (33.3)					
Rest of World							
Tralokinumab Q2W + TCS	112	53 (47.3)	10.4 (-2.31;23.15)	1.3 (0.94; 1.74)	1.5 (0.91; 2.61)	0.1113	
Placebo + TCS	117	43 (36.8)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

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Table 1.16.331.4.1: Total, Region, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	137	85 (62.0)	11.3 (-0.46;23.02)	1.2 (0.99; 1.51)	1.6 (0.98; 2.55)	0.0614	0.5613
Placebo + TCS	136	69 (50.7)					
Germany							
Tralokinumab Q2W + TCS	22	13 (59.1)	19.7 (-12.7;52.15)	1.5 (0.72; 3.26)	2.1 (0.61; 6.97)	0.2432	
Placebo + TCS	18	7 (38.9)					
Rest of World							
Tralokinumab Q2W + TCS	115	72 (62.6)	10.0 (-2.75;22.69)	1.2 (0.95; 1.49)	1.5 (0.89; 2.53)	0.1261	
Placebo + TCS	118	62 (52.5)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 3.

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Table 1.16.333.4.1: Total, Region, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	135	105 (77.8)	18.9 (8.08;29.81)	1.3 (1.12; 1.56)	2.5 (1.44; 4.20)	0.0009	0.7463
Placebo + TCS	134	79 (59.0)					
Germany							
Tralokinumab Q2W + TCS	22	17 (77.3)	22.3 (-8.08;52.70)	1.4 (0.84; 2.39)	2.7 (0.68;10.52)	0.1646	
Placebo + TCS	17	9 (52.9)					
Rest of World							
Tralokinumab Q2W + TCS	113	88 (77.9)	18.3 (6.55;30.03)	1.3 (1.09; 1.56)	2.4 (1.34; 4.28)	0.0031	
Placebo + TCS	117	70 (59.8)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

Table 1.16.335.4.1: Total, Region, DLQI 0/1, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	32 (23.2)	6.9 (-2.56;16.32)	1.4 (0.87; 2.35)	1.5 (0.85; 2.81)	0.1545	0.6282
Placebo + TCS	136	22 (16.2)					
Germany							
Tralokinumab Q2W + TCS	22	5 (22.7)	12.1 (-11.3;35.46)	2.1 (0.43;10.67)	2.4 (0.40;13.99)	0.3424	
Placebo + TCS	18	2 (11.1)					
Rest of World							
Tralokinumab Q2W + TCS	116	27 (23.3)	6.2 (-4.09;16.52)	1.4 (0.80; 2.34)	1.5 (0.77; 2.80)	0.2392	
Placebo + TCS	118	20 (16.9)					

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 Prior CSA use and baseline IGA.

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Table 1.16.355.4.1: Total, Region, EASI 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	96 (69.6)	16.8 (5.65;27.89)	1.3 (1.09; 1.59)	2.1 (1.27; 3.49)	0.0039	0.5462
Placebo + TCS	137	73 (53.3)					
Germany							
Tralokinumab Q2W + TCS	22	14 (63.6)	6.3 (-24.0;36.49)	1.1 (0.66; 1.88)	1.3 (0.35; 4.90)	0.6850	
Placebo + TCS	18	10 (55.6)					
Rest of World							
Tralokinumab Q2W + TCS	116	82 (70.7)	18.1 (6.09;30.09)	1.3 (1.10; 1.65)	2.2 (1.29; 3.89)	0.0040	
Placebo + TCS	119	63 (52.9)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.16.356.4.1: Total, Region, EASI 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	67 (48.6)	14.1 (2.87;25.40)	1.4 (1.06; 1.86)	1.8 (1.12; 3.04)	0.0160	0.2692
Placebo + TCS	137	48 (35.0)					
Germany							
Tralokinumab Q2W + TCS	22	8 (36.4)	-1.4 (-30.8;27.97)	1.0 (0.42; 2.18)	0.9 (0.24; 3.63)	0.9280	
Placebo + TCS	18	7 (38.9)					
Rest of World							
Tralokinumab Q2W + TCS	116	59 (50.9)	17.4 (5.18;29.52)	1.5 (1.12; 2.04)	2.1 (1.23; 3.65)	0.0066	
Placebo + TCS	119	41 (34.5)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.16.359.4.1: Total, Region, SCORAD 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	53 (38.4)	20.6 (10.39;30.82)	2.1 (1.42; 3.22)	3.0 (1.68; 5.21)	0.0001	0.3792
Placebo + TCS	137	25 (18.2)					
Germany							
Tralokinumab Q2W + TCS	22	9 (40.9)	30.3 (5.49;55.03)	3.8 (0.92;16.06)	6.4 (1.04;39.20)	0.0416	
Placebo + TCS	18	2 (11.1)					
Rest of World							
Tralokinumab Q2W + TCS	116	44 (37.9)	19.5 (8.38;30.58)	2.0 (1.32; 3.15)	2.8 (1.51; 5.12)	0.0008	
Placebo + TCS	119	23 (19.3)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.16.360.4.1: Total, Region, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	134	64 (47.8)	8.3 (-3.43;20.09)	1.2 (0.92; 1.60)	1.4 (0.87; 2.29)	0.1650	0.6553
Placebo + TCS	135	53 (39.3)					
Germany							
Tralokinumab Q2W + TCS	22	9 (40.9)	6.0 (-24.7;36.71)	1.2 (0.54; 2.52)	1.3 (0.35; 4.68)	0.7103	
Placebo + TCS	18	7 (38.9)					
Rest of World							
Tralokinumab Q2W + TCS	112	55 (49.1)	9.3 (-3.53;22.08)	1.2 (0.92; 1.66)	1.5 (0.86; 2.47)	0.1558	
Placebo + TCS	117	46 (39.3)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.16.361.4.1: Total, Region, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	137	86 (62.8)	16.0 (4.45;27.60)	1.3 (1.08; 1.67)	1.9 (1.19; 3.16)	0.0078	0.6445
Placebo + TCS	136	64 (47.1)					
Germany							
Tralokinumab Q2W + TCS	22	13 (59.1)	11.3 (-20.4;43.00)	1.2 (0.66; 2.30)	1.6 (0.44; 5.45)	0.4921	
Placebo + TCS	18	9 (50.0)					
Rest of World							
Tralokinumab Q2W + TCS	115	73 (63.5)	17.2 (4.69;29.78)	1.4 (1.08; 1.74)	2.0 (1.20; 3.45)	0.0085	
Placebo + TCS	118	55 (46.6)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.16.363.4.1: Total, Region, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	135	105 (77.8)	21.3 (10.39;32.18)	1.4 (1.16; 1.64)	2.7 (1.59; 4.63)	0.0002	0.5477
Placebo + TCS	134	76 (56.7)					
Germany							
Tralokinumab Q2W + TCS	22	18 (81.8)	27.6 (-0.97;56.26)	1.5 (0.93; 2.48)	4.0 (0.87;17.96)	0.0678	
Placebo + TCS	17	9 (52.9)					
Rest of World							
Tralokinumab Q2W + TCS	113	87 (77.0)	19.7 (7.83;31.62)	1.3 (1.11; 1.62)	2.5 (1.41; 4.42)	0.0016	
Placebo + TCS	117	67 (57.3)					

Treatment policy estimand: Missing values at Week 26 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.

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Table 1.16.365.4.1: Total, Region, DLQI 0/1, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	36 (26.1)	13.7 (4.62;22.81)	2.1 (1.25; 3.56)	2.5 (1.34; 4.85)	0.0038	0.4960
Placebo + TCS	136	17 (12.5)					
Germany							
Tralokinumab Q2W + TCS	22	5 (22.7)	9.1 (-15.5;33.72)	1.6 (0.44; 5.66)	1.8 (0.35; 9.30)	0.4848	
Placebo + TCS	18	3 (16.7)					
Rest of World							
Tralokinumab Q2W + TCS	116	31 (26.7)	14.8 (4.88;24.67)	2.2 (1.26; 3.99)	2.7 (1.36; 5.50)	0.0042	
Placebo + TCS	118	14 (11.9)					

Treatment policy estimand: Missing values at Week 26 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.

Table 1.16.385.4.1: Total, Region, SCORAD 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	13 (9.4)	4.5 (-1.61;10.59)	1.9 (0.78; 4.54)	2.0 (0.77; 5.17)	0.1522	0.1057
Placebo + TCS	137	7 (5.1)					
Germany							
Tralokinumab Q2W + TCS	22	0 (0.0)	-5.2 (-15.5; 5.15)	0.0 (Not estimable)	0.0 (Not estimable)	0.3173	
Placebo + TCS	18	1 (5.6)					
Rest of World							
Tralokinumab Q2W + TCS	116	13 (11.2)	6.6 (-0.40;13.64)	2.3 (0.93; 5.78)	2.5 (0.92; 6.80)	0.0631	
Placebo + TCS	119	6 (5.0)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

Table 1.16.389.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)							
Total							
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)		
Week 16		123 4.2 (2.30)			124 3.3 (2.05)		
Week 16 chg		122 -3.3 (2.36)	-3.21 (0.19)		123 -3.9 (2.06)	-3.98 (0.19)	-0.77 (-1.30, -0.24) 0.004 [-0.35 (-0.60, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9715
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.389.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 7.9 (1.35)		22	22 7.1 (1.41)		
Week 16		14 4.6 (2.77)			17 3.3 (2.14)		
Week 16 chg		14 -3.4 (3.21)	-3.05 (0.70)		17 -3.7 (1.96)	-4.00 (0.64)	-0.95 (-2.95, 1.05) 0.339 [-0.36 (-1.08, 0.35)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9715
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.389.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	119	118 7.4 (1.37)		116	115 7.3 (1.47)			
Week 16		109 4.2 (2.24)			107 3.4 (2.04)			
Week 16 chg		108 -3.3 (2.24)	-3.22 (0.20)		106 -4.0 (2.08)	-3.99 (0.20)	-0.77 (-1.32, -0.21) [-0.36 (-0.63, -0.09)]	0.007

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9715
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.390.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)									
Total									
Baseline	137	136	6.9 (1.64)		138	137	6.3 (2.11)		
Week 16		123	3.2 (2.41)			124	2.4 (2.16)		
Week 16 chg		122	-3.7 (2.29)	-3.50 (0.19)		123	-3.9 (2.32)	-4.03 (0.19)	-0.53 (-1.07, 0.01) 0.052 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6913
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.390.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 7.3 (1.71)		22	22 6.1 (1.80)		
Week 16		14 3.4 (2.94)			17 1.9 (1.85)		
Week 16 chg		14 -4.0 (2.91)	-3.60 (0.66)		17 -4.2 (2.18)	-4.63 (0.60)	-1.03 (-2.93, 0.86) 0.272 [-0.41 (-1.12, 0.31)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6913
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.390.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World												
Baseline	119	118	6.8 (1.63)			116	115	6.3 (2.17)				
Week 16		109	3.2 (2.35)				107	2.5 (2.21)				
Week 16 chg		108	-3.6 (2.21)	-3.48	(0.20)		106	-3.8 (2.34)	-3.95	(0.20)	-0.47 (-1.04, 0.09) [-0.21 (-0.48, 0.06)]	0.102

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6913
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.391.4.1: Total, Region, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score											
Total											
Baseline	137	137	70.8 (12.84)			138	138	70.2 (12.05)			
Week 16		124	36.3 (18.78)				123	27.0 (16.90)			
Week 16 chg		124	-34.7 (19.94)	-34.36	(1.54)		123	-43.3 (19.46)	-43.61	(1.55)	-9.25 (-13.6, -4.94) <.001 [-0.47 (-0.72, -0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9177
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.391.4.1: Total, Region, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 69.5 (9.23)		22	22 67.2 (6.09)		
Week 16		17 36.6 (23.16)			19 24.9 (9.31)		
Week 16 chg		17 -33.1 (22.89)	-32.52 (4.23)		19 -41.6 (11.31)	-42.07 (4.01)	-9.55 (-21.7, 2.56) 0.118 [-0.54 (-1.20, 0.13)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9177
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.391.4.1: Total, Region, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 71.0 (13.32)		116	116 70.7 (12.81)		
Week 16		107 36.3 (18.11)			104 27.3 (17.95)		
Week 16 chg		107 -35.0 (19.53)	-34.66 (1.68)		104 -43.6 (20.63)	-43.89 (1.70)	-9.23 (-13.9, -4.52) <.001 [-0.46 (-0.73, -0.19)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9177
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.392.4.1: Total, Region, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 16		122 6.4 (5.60)			119 4.5 (3.87)		
Week 16 chg		120 -10.0 (6.54)	-9.61 (0.40)		118 -11.0 (5.99)	-11.29 (0.41)	-1.68 (-2.82, -0.55) 0.004 [-0.27 (-0.52, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7704
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.392.4.1: Total, Region, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Germany								
Baseline	18	17 16.0 (7.96)		22	22 16.1 (5.18)			
Week 16		17 6.7 (5.83)			19 5.0 (5.17)			
Week 16 chg		16 -9.0 (8.91)	-9.06 (1.38)		19 -11.0 (5.79)	-10.96 (1.27)	-1.90 (-5.76, 1.96) [-0.26 (-0.93, 0.41)]	0.322

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7704
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.392.4.1: Total, Region, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	117 16.4 (6.10)		116	115 15.8 (6.78)		
Week 16		105 6.4 (5.59)			100 4.4 (3.59)		
Week 16 chg		104 -10.1 (6.14)	-9.70 (0.42)		99 -10.9 (6.06)	-11.35 (0.43)	-1.66 (-2.85, -0.47) 0.006 [-0.27 (-0.55, 0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7704
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.393.4.1: Total, Region, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 16		122 12.9 (7.67)			119 9.0 (5.53)			
Week 16 chg		120 -8.0 (8.09)	-8.10 (0.59)		116 -12.2 (6.39)	-12.12 (0.60)	-4.02 (-5.68, -2.36) [-0.55 (-0.81, -0.29)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4965
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.393.4.1: Total, Region, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 21.5 (6.18)		22	22 22.5 (4.35)		
Week 16		17 13.8 (8.33)			19 10.3 (6.34)		
Week 16 chg		16 -6.9 (8.93)	-7.24 (1.81)		19 -11.9 (7.29)	-11.76 (1.66)	-4.52 (-9.58, 0.54) 0.078 [-0.56 (-1.24, 0.12)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4965
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.393.4.1: Total, Region, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World												
Baseline	119	117	20.8 (5.67)			116	113	21.0 (5.25)				
Week 16		105	12.8 (7.59)				100	8.7 (5.36)				
Week 16 chg		104	-8.2 (7.99)	-8.19	(0.62)		97	-12.3 (6.24)	-12.24	(0.65)	-4.04 (-5.82, -2.27) [-0.56 (-0.84, -0.28)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4965
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.395.4.1: Total, Region, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 16		122	69.3 (21.69)			119	75.7 (16.92)		
Week 16 chg		120	16.7 (26.74)	14.64 (1.75)		116	17.7 (22.49)	19.84 (1.78)	5.21 (0.28, 10.14) 0.039 [0.21 (-0.05, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7796
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.395.4.1: Total, Region, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany											
Baseline	18	17	46.9 (24.54)			22	22	47.8 (17.23)			
Week 16		17	67.5 (24.71)				19	75.5 (19.22)			
Week 16 chg		16	18.5 (40.28)	16.42	(5.45)		19	25.7 (27.04)	27.90	(5.02)	11.47 (-3.76, 26.71) 0.134 [0.34 (-0.33, 1.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7796
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.395.4.1: Total, Region, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	117	53.3 (21.57)			116	113	58.3 (20.00)			
Week 16		105	69.6 (21.28)				100	75.8 (16.56)			
Week 16 chg		104	16.4 (24.28)	14.30	(1.80)		97	16.1 (21.29)	18.35	(1.87)	4.06 (-1.09, 9.20) 0.122 [0.18 (-0.10, 0.45)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7796
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.396.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss									
Total									
Baseline	137	137	6.7 (2.21)		138	138	6.7 (2.36)		
Week 16		124	2.7 (2.77)			123	1.9 (2.39)		
Week 16 chg		124	-4.1 (3.25)	-3.99 (0.23)		123	-4.7 (2.92)	-4.72 (0.23)	-0.73 (-1.36, -0.09) 0.025 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5996
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.396.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 7.1 (2.27)		22	22 6.7 (2.09)		
Week 16		17 3.2 (3.13)			19 1.4 (1.88)		
Week 16 chg		17 -3.9 (3.52)	-3.71 (0.63)		19 -5.1 (2.35)	-5.25 (0.60)	-1.54 (-3.33, 0.25) 0.090 [-0.52 (-1.18, 0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5996
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.396.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 6.7 (2.20)		116	116 6.7 (2.42)		
Week 16		107 2.6 (2.72)			104 2.0 (2.47)		
Week 16 chg		107 -4.1 (3.23)	-4.03 (0.25)		104 -4.6 (3.02)	-4.62 (0.25)	-0.59 (-1.28, 0.10) 0.095 [-0.19 (-0.46, 0.08)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5996
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.398.4.1: Total, Region, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 26		115	72.6 (20.73)			119	76.4 (17.30)		
Week 26 chg		113	20.5 (25.83)	18.74 (1.72)		116	19.5 (21.18)	21.31 (1.70)	2.56 (-2.22, 7.35) 0.292 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6509
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.398.4.1: Total, Region, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany											
Baseline	18	17	46.9 (24.54)			22	22	47.8 (17.23)			
Week 26		15	75.2 (17.94)				18	76.3 (13.45)			
Week 26 chg		14	28.7 (31.18)	25.93	(4.28)		18	26.6 (24.12)	29.19	(3.83)	3.26 (-8.58, 15.09) 0.577 [0.12 (-0.58, 0.82)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6509
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.398.4.1: Total, Region, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World									
Baseline	119	117	53.3 (21.57)		116	113	58.3 (20.00)		
Week 26		100	72.2 (21.17)			101	76.4 (17.96)		
Week 26 chg		99	19.4 (24.96)	17.58 (1.86)		98	18.2 (20.46)	20.01 (1.87)	2.43 (-2.80, 7.66) 0.361 [0.11 (-0.17, 0.39)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6509
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.401.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score											
Total											
Baseline	137	137	33.8 (13.46)			138	138	32.1 (11.53)			
Week 2		137	20.9 (13.94)				138	19.2 (12.75)			
Week 2 chg		137	-12.9 (11.16)	-12.56	(0.82)		138	-12.9 (10.72)	-13.28	(0.82)	-0.72 (-3.02, 1.57) 0.536 [-0.07 (-0.30, 0.17)]
Week 4		134	15.7 (12.58)				137	13.1 (10.37)			
Week 4 chg		134	-18.2 (11.93)	-17.48	(0.83)		137	-18.8 (10.58)	-19.37	(0.82)	-1.88 (-4.18, 0.42) 0.109 [-0.17 (-0.41, 0.07)]
Week 6		132	14.7 (12.40)				134	11.2 (9.67)			
Week 6 chg		132	-19.2 (12.62)	-18.42	(0.83)		134	-20.9 (11.93)	-21.43	(0.83)	-3.01 (-5.32, -0.70) 0.011 [-0.25 (-0.49, -0.00)]
Week 8		133	14.0 (12.73)				130	9.6 (8.49)			
Week 8 chg		133	-19.9 (13.84)	-19.19	(0.83)		130	-22.5 (12.16)	-23.11	(0.83)	-3.92 (-6.23, -1.60) <.001 [-0.30 (-0.54, -0.06)]
Week 10		131	12.5 (11.67)				130	7.6 (7.43)			
Week 10 chg		131	-21.5 (13.93)	-20.50	(0.83)		130	-24.3 (11.55)	-24.96	(0.83)	-4.46 (-6.78, -2.14) <.001 [-0.35 (-0.59, -0.10)]
Week 12		128	12.0 (11.20)				128	7.6 (7.85)			
Week 12 chg		128	-22.2 (14.26)	-20.99	(0.84)		128	-24.7 (12.40)	-25.11	(0.84)	-4.13 (-6.46, -1.80) <.001 [-0.31 (-0.56, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9485
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.401.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 11.2 (11.57)			127 7.0 (8.34)		
Week 14 chg		126 -22.8 (14.69)	-21.74 (0.84)		127 -25.1 (13.29)	-25.62 (0.84)	-3.87 (-6.21, -1.54) 0.001 [-0.28 (-0.52, -0.03)]
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.54 (0.84)		123 -25.9 (12.78)	-26.06 (0.84)	-3.52 (-5.86, -1.17) 0.003 [-0.25 (-0.50, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9485
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.401.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 28.6 (7.70)		22	22 28.9 (7.99)		
Week 2		18 16.9 (10.44)			22 17.1 (10.70)		
Week 2 chg		18 -11.7 (9.36)	-11.66 (2.02)		22 -11.8 (5.57)	-11.81 (1.83)	-0.15 (-5.60, 5.29) 0.955 [-0.02 (-0.64, 0.60)]
Week 4		17 12.8 (11.45)			22 12.7 (8.19)		
Week 4 chg		17 -16.3 (10.67)	-16.07 (2.05)		22 -16.2 (7.98)	-16.18 (1.83)	-0.12 (-5.61, 5.38) 0.966 [-0.01 (-0.65, 0.62)]
Week 6		17 12.1 (13.04)			22 11.2 (7.50)		
Week 6 chg		17 -17.0 (11.99)	-16.76 (2.05)		22 -17.7 (8.62)	-17.66 (1.83)	-0.90 (-6.40, 4.59) 0.744 [-0.09 (-0.72, 0.55)]
Week 8		17 13.5 (13.52)			20 8.3 (4.46)		
Week 8 chg		17 -15.6 (12.31)	-15.32 (2.05)		20 -20.0 (8.76)	-19.91 (1.87)	-4.59 (-10.1, 0.96) 0.104 [-0.44 (-1.09, 0.22)]
Week 10		17 12.8 (13.17)			20 6.6 (4.91)		
Week 10 chg		17 -16.3 (11.90)	-15.98 (2.05)		20 -21.7 (8.14)	-21.61 (1.87)	-5.63 (-11.2, -0.09) 0.047 [-0.56 (-1.22, 0.10)]
Week 12		16 12.0 (13.56)			19 6.4 (5.90)		
Week 12 chg		16 -17.2 (12.63)	-16.42 (2.08)		19 -22.3 (9.42)	-21.95 (1.88)	-5.53 (-11.1, 0.08) 0.053 [-0.50 (-1.18, 0.17)]
Week 14		17 11.9 (14.68)			19 5.2 (3.35)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9485
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.401.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	17	-17.2 (13.06)	-16.88 (2.05)	19	-22.8 (8.40)	-22.42 (1.89)	-5.54 (-11.1, 0.03) 0.051 [-0.51 (-1.18, 0.15)]
Week 16	17	11.2 (14.59)		19	4.4 (2.89)		
Week 16 chg	17	-17.9 (13.49)	-17.58 (2.05)	19	-23.6 (8.55)	-23.26 (1.89)	-5.68 (-11.3, -0.11) 0.046 [-0.51 (-1.17, 0.16)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9485
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.401.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 34.6 (13.98)		116	116 32.7 (12.01)		
Week 2		119 21.6 (14.33)			116 19.6 (13.11)		
Week 2 chg		119 -13.1 (11.43)	-12.70 (0.90)		116 -13.1 (11.44)	-13.54 (0.91)	-0.84 (-3.37, 1.68) 0.513 [-0.07 (-0.33, 0.18)]
Week 4		117 16.1 (12.73)			115 13.2 (10.77)		
Week 4 chg		117 -18.5 (12.12)	-17.73 (0.90)		115 -19.3 (10.97)	-19.92 (0.92)	-2.18 (-4.72, 0.35) 0.091 [-0.19 (-0.45, 0.07)]
Week 6		115 15.1 (12.32)			112 11.2 (10.07)		
Week 6 chg		115 -19.6 (12.73)	-18.71 (0.91)		112 -21.5 (12.41)	-22.10 (0.92)	-3.38 (-5.93, -0.84) 0.009 [-0.27 (-0.53, -0.01)]
Week 8		116 14.1 (12.67)			110 9.8 (9.03)		
Week 8 chg		116 -20.5 (13.99)	-19.81 (0.91)		110 -23.0 (12.66)	-23.66 (0.92)	-3.85 (-6.40, -1.30) 0.003 [-0.29 (-0.55, -0.03)]
Week 10		114 12.5 (11.49)			110 7.8 (7.80)		
Week 10 chg		114 -22.2 (14.09)	-21.23 (0.91)		110 -24.7 (12.04)	-25.53 (0.92)	-4.30 (-6.86, -1.75) 0.001 [-0.33 (-0.59, -0.06)]
Week 12		112 12.0 (10.90)			109 7.8 (8.14)		
Week 12 chg		112 -22.9 (14.39)	-21.72 (0.91)		109 -25.1 (12.83)	-25.65 (0.93)	-3.93 (-6.49, -1.37) 0.003 [-0.29 (-0.55, -0.02)]
Week 14		109 11.1 (11.08)			108 7.3 (8.91)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9485
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

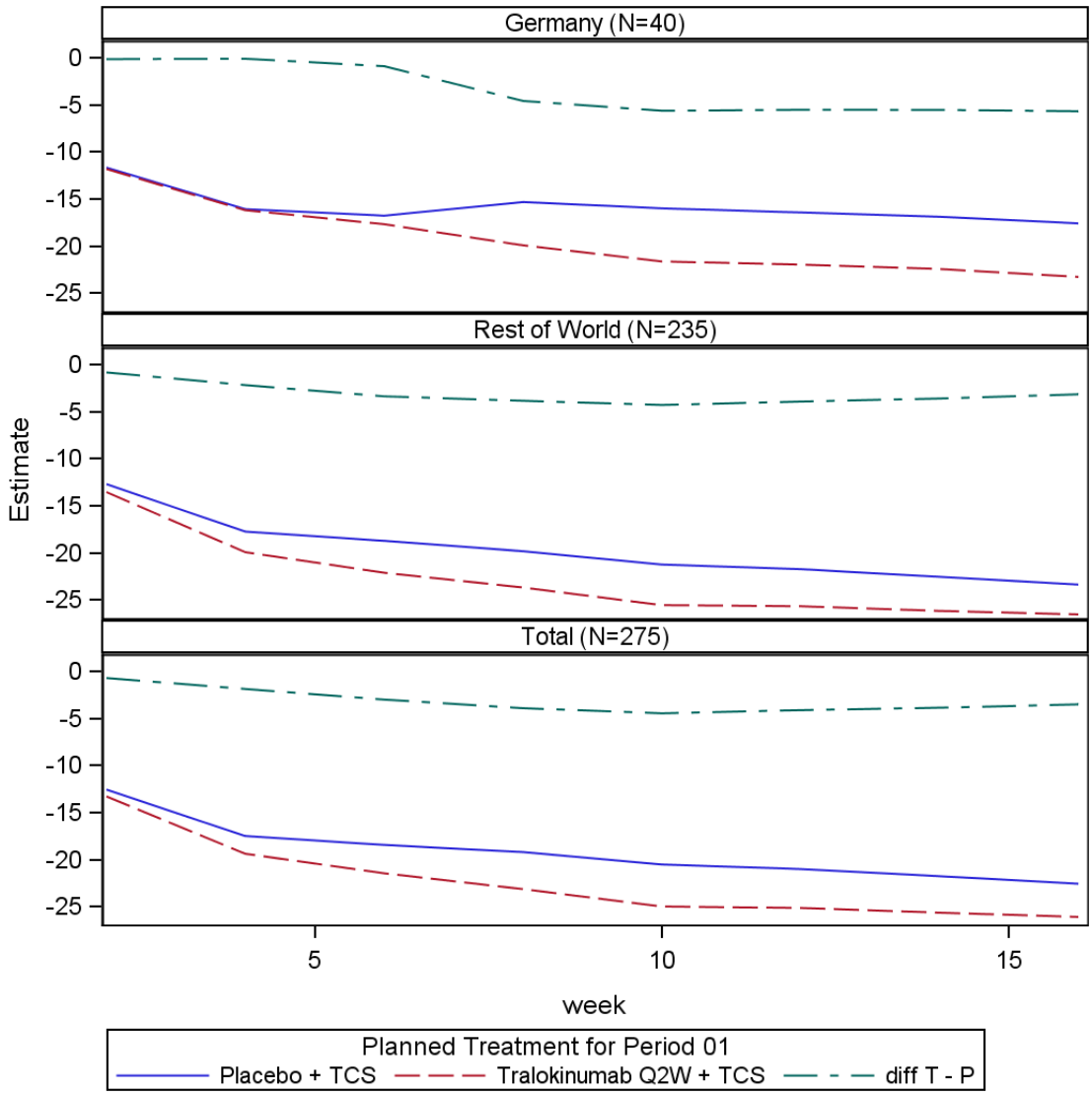
12MAY21 16:21 LP0162-Payer /p_mmrm3/t_t_reg3_g01_46_w16.txt

Table 1.16.401.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	-23.7 (14.79)	-22.53 (0.92)	108	-25.5 (13.96)	-26.14 (0.93)	-3.61 (-6.18, -1.04) [-0.25 (-0.52, 0.02)]	0.006
Week 16	107	10.4 (10.92)		104	6.8 (8.16)			
Week 16 chg	107	-24.7 (15.00)	-23.35 (0.92)	104	-26.3 (13.40)	-26.51 (0.93)	-3.17 (-5.75, -0.58) [-0.22 (-0.49, 0.05)]	0.016

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9485
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.401.4.2: Total, Region, change in EASI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.16.403.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Worst Pruritus (eDiary)										
Total										
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)			
Week 1		135	6.3 (1.69)			136	6.0 (1.78)			
Week 1 chg		135	-1.1 (1.34)	-1.14 (0.17)		136	-1.2 (1.31)	-1.23 (0.17)	-0.08 (-0.56, 0.39) [-0.06 (-0.30, 0.18)]	0.732
Week 2		134	5.8 (1.97)			132	5.4 (2.11)			
Week 2 chg		134	-1.7 (1.78)	-1.67 (0.17)		132	-1.9 (1.67)	-1.92 (0.17)	-0.24 (-0.72, 0.24) [-0.14 (-0.38, 0.10)]	0.324
Week 3		133	5.3 (2.17)			131	4.8 (2.08)			
Week 3 chg		133	-2.2 (2.12)	-2.11 (0.17)		131	-2.5 (1.84)	-2.53 (0.17)	-0.42 (-0.90, 0.06) [-0.21 (-0.45, 0.03)]	0.088
Week 4		130	5.1 (2.25)			133	4.4 (2.14)			
Week 4 chg		130	-2.4 (2.14)	-2.29 (0.17)		133	-2.8 (1.92)	-2.87 (0.17)	-0.58 (-1.06, -0.10) [-0.28 (-0.53, -0.04)]	0.019
Week 5		131	4.9 (2.37)			129	4.2 (2.15)			
Week 5 chg		131	-2.6 (2.26)	-2.54 (0.17)		129	-3.1 (1.92)	-3.16 (0.17)	-0.62 (-1.10, -0.14) [-0.30 (-0.54, -0.05)]	0.012
Week 6		130	4.8 (2.35)			129	4.2 (2.16)			
Week 6 chg		130	-2.7 (2.25)	-2.58 (0.17)		129	-3.1 (1.99)	-3.14 (0.17)	-0.57 (-1.05, -0.08) [-0.27 (-0.51, -0.02)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2155
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.403.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	4.7 (2.24)		128	4.0 (2.13)			
Week 7 chg	129	-2.8 (2.25)	-2.73 (0.17)	128	-3.3 (2.05)	-3.38 (0.17)	-0.65 (-1.13, -0.16) [-0.30 (-0.55, -0.05)]	0.009
Week 8	127	4.7 (2.32)		125	3.7 (2.10)			
Week 8 chg	127	-2.8 (2.27)	-2.73 (0.17)	125	-3.7 (1.96)	-3.64 (0.17)	-0.92 (-1.40, -0.43) [-0.43 (-0.68, -0.18)]	<.001
Week 9	127	4.6 (2.37)		127	3.6 (2.10)			
Week 9 chg	127	-2.9 (2.32)	-2.79 (0.17)	127	-3.7 (2.03)	-3.71 (0.17)	-0.92 (-1.40, -0.44) [-0.42 (-0.67, -0.17)]	<.001
Week 10	125	4.5 (2.42)		122	3.6 (2.11)			
Week 10 chg	125	-2.9 (2.39)	-2.87 (0.17)	122	-3.7 (1.93)	-3.70 (0.17)	-0.83 (-1.32, -0.35) [-0.38 (-0.63, -0.13)]	<.001
Week 11	128	4.4 (2.41)		126	3.5 (2.15)			
Week 11 chg	128	-3.1 (2.40)	-3.06 (0.17)	126	-3.7 (1.97)	-3.75 (0.17)	-0.70 (-1.18, -0.21) [-0.32 (-0.56, -0.07)]	0.005
Week 12	123	4.4 (2.36)		121	3.5 (2.08)			
Week 12 chg	123	-3.1 (2.41)	-3.03 (0.17)	121	-3.8 (2.06)	-3.82 (0.17)	-0.80 (-1.28, -0.31) [-0.35 (-0.61, -0.10)]	0.001
Week 13	116	4.3 (2.38)		120	3.3 (2.06)			
Week 13 chg	116	-3.3 (2.35)	-3.09 (0.18)	120	-4.0 (2.09)	-3.92 (0.17)	-0.84 (-1.32, -0.35) [-0.38 (-0.63, -0.12)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2155
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.403.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.13 (0.17)	123	-3.9 (2.12)	-3.85 (0.17)	-0.72 (-1.20, -0.23) [-0.32 (-0.57, -0.07)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.16 (0.17)	123	-4.0 (2.15)	-3.93 (0.17)	-0.76 (-1.25, -0.28) [-0.34 (-0.59, -0.09)]	0.002
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.10 (0.17)	122	-3.9 (2.06)	-3.93 (0.17)	-0.83 (-1.32, -0.35) [-0.38 (-0.63, -0.12)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2155
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.403.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 7.9 (1.35)		22	22 7.1 (1.41)		
Week 1		18 6.5 (1.62)			21 5.9 (1.94)		
Week 1 chg		18 -1.4 (1.43)	-1.33 (0.54)		21 -1.2 (1.18)	-1.18 (0.49)	0.14 (-1.36, 1.65) 0.848 [0.11 (-0.52, 0.74)]
Week 2		18 5.8 (2.46)			21 5.3 (1.84)		
Week 2 chg		18 -2.1 (2.42)	-2.01 (0.54)		21 -1.8 (1.18)	-1.92 (0.49)	0.08 (-1.42, 1.59) 0.911 [0.05 (-0.58, 0.68)]
Week 3		17 5.4 (2.44)			21 4.9 (2.02)		
Week 3 chg		17 -2.5 (2.56)	-2.21 (0.55)		21 -2.2 (1.52)	-2.38 (0.49)	-0.17 (-1.68, 1.35) 0.826 [-0.08 (-0.72, 0.56)]
Week 4		17 5.2 (2.86)			21 4.5 (1.89)		
Week 4 chg		17 -2.7 (2.55)	-2.48 (0.55)		21 -2.6 (1.59)	-2.73 (0.49)	-0.25 (-1.76, 1.26) 0.741 [-0.12 (-0.76, 0.52)]
Week 5		17 4.7 (2.96)			22 4.2 (1.96)		
Week 5 chg		17 -3.2 (2.77)	-2.93 (0.55)		22 -2.9 (1.76)	-2.99 (0.49)	-0.06 (-1.57, 1.45) 0.938 [-0.03 (-0.66, 0.61)]
Week 6		17 4.9 (2.71)			20 4.5 (2.06)		
Week 6 chg		17 -3.0 (2.54)	-2.72 (0.55)		20 -2.6 (1.84)	-2.88 (0.49)	-0.16 (-1.68, 1.35) 0.829 [-0.07 (-0.72, 0.57)]
Week 7		17 4.6 (2.70)			20 4.0 (2.26)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2155
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.403.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	17	-3.3 (2.61)	-2.94 (0.55)	20	-3.1 (2.06)	-3.33 (0.49)	-0.39 (-1.90, 1.13) 0.609 [-0.17 (-0.81, 0.48)]
Week 8	17	4.8 (2.97)		20	3.7 (2.15)		
Week 8 chg	17	-3.2 (3.00)	-2.80 (0.55)	20	-3.5 (1.93)	-3.66 (0.49)	-0.86 (-2.38, 0.65) 0.258 [-0.35 (-1.00, 0.30)]
Week 9	16	5.0 (2.85)		20	3.6 (2.06)		
Week 9 chg	16	-2.9 (2.96)	-2.61 (0.55)	20	-3.6 (2.14)	-3.64 (0.49)	-1.04 (-2.55, 0.48) 0.176 [-0.41 (-1.07, 0.26)]
Week 10	15	5.4 (2.92)		19	3.4 (2.12)		
Week 10 chg	15	-2.6 (3.12)	-2.48 (0.56)	19	-3.7 (1.95)	-3.85 (0.50)	-1.37 (-2.90, 0.16) 0.078 [-0.54 (-1.23, 0.15)]
Week 11	16	5.2 (2.91)		19	3.3 (2.35)		
Week 11 chg	16	-2.7 (3.03)	-2.47 (0.55)	19	-3.8 (2.01)	-3.88 (0.50)	-1.40 (-2.92, 0.12) 0.070 [-0.56 (-1.23, 0.12)]
Week 12	14	4.4 (2.74)		18	3.4 (2.07)		
Week 12 chg	14	-3.3 (3.21)	-2.87 (0.56)	18	-3.7 (1.87)	-3.97 (0.50)	-1.11 (-2.64, 0.43) 0.154 [-0.43 (-1.14, 0.27)]
Week 13	13	5.0 (2.92)		17	2.6 (1.34)		
Week 13 chg	13	-2.7 (3.43)	-2.47 (0.56)	17	-4.3 (1.50)	-4.43 (0.50)	-1.96 (-3.51, -0.42) 0.014 [-0.78 (-1.53, -0.03)]
Week 14	14	4.9 (2.66)		16	2.8 (2.00)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2155
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.403.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	14	-2.9 (3.03)	-2.74 (0.56)	16	-4.4 (1.46)	-4.10 (0.51)	-1.37 (-2.91, 0.17) [-0.59 (-1.32, 0.14)]	0.081
Week 15	16	4.8 (2.68)		17	3.2 (2.06)			
Week 15 chg	16	-3.1 (2.90)	-2.85 (0.55)	17	-3.8 (1.97)	-3.82 (0.50)	-0.97 (-2.50, 0.57) [-0.39 (-1.08, 0.30)]	0.212
Week 16	14	4.6 (2.77)		17	3.3 (2.14)			
Week 16 chg	14	-3.4 (3.21)	-2.87 (0.56)	17	-3.7 (1.96)	-3.75 (0.50)	-0.89 (-2.43, 0.66) [-0.34 (-1.05, 0.37)]	0.255

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2155
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.403.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	118 7.4 (1.37)		116	115 7.3 (1.47)		
Week 1		117 6.3 (1.71)			115 6.1 (1.76)		
Week 1 chg		117 -1.1 (1.33)	-1.12 (0.18)		115 -1.2 (1.34)	-1.23 (0.18)	-0.11 (-0.62, 0.40) 0.672 [-0.08 (-0.34, 0.18)]
Week 2		116 5.8 (1.90)			111 5.4 (2.16)		
Week 2 chg		116 -1.6 (1.66)	-1.62 (0.18)		111 -1.9 (1.75)	-1.92 (0.19)	-0.30 (-0.81, 0.22) 0.255 [-0.17 (-0.43, 0.09)]
Week 3		116 5.3 (2.13)			110 4.7 (2.10)		
Week 3 chg		116 -2.1 (2.05)	-2.09 (0.18)		110 -2.6 (1.89)	-2.56 (0.19)	-0.47 (-0.98, 0.04) 0.073 [-0.24 (-0.50, 0.02)]
Week 4		113 5.1 (2.16)			112 4.4 (2.19)		
Week 4 chg		113 -2.3 (2.08)	-2.27 (0.18)		112 -2.9 (1.98)	-2.89 (0.19)	-0.62 (-1.14, -0.11) 0.017 [-0.31 (-0.57, -0.04)]
Week 5		114 4.9 (2.28)			107 4.2 (2.20)		
Week 5 chg		114 -2.6 (2.18)	-2.48 (0.18)		107 -3.2 (1.96)	-3.20 (0.19)	-0.71 (-1.23, -0.20) 0.007 [-0.34 (-0.61, -0.08)]
Week 6		113 4.8 (2.30)			109 4.2 (2.18)		
Week 6 chg		113 -2.6 (2.21)	-2.56 (0.18)		109 -3.2 (2.01)	-3.20 (0.19)	-0.64 (-1.15, -0.13) 0.015 [-0.30 (-0.57, -0.04)]
Week 7		112 4.7 (2.18)			108 4.0 (2.12)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2155
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.403.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	112	-2.8 (2.19)	-2.70 (0.18)	108	-3.4 (2.06)	-3.38 (0.19)	-0.68 (-1.20, -0.17) [-0.32 (-0.59, -0.06)]	0.009
Week 8	110	4.7 (2.22)		105	3.7 (2.10)			
Week 8 chg	110	-2.8 (2.14)	-2.71 (0.18)	105	-3.7 (1.97)	-3.65 (0.19)	-0.94 (-1.45, -0.42) [-0.45 (-0.73, -0.18)]	<.001
Week 9	111	4.6 (2.31)		107	3.6 (2.12)			
Week 9 chg	111	-2.9 (2.23)	-2.80 (0.18)	107	-3.7 (2.01)	-3.73 (0.19)	-0.93 (-1.45, -0.42) [-0.44 (-0.71, -0.17)]	<.001
Week 10	110	4.4 (2.33)		103	3.7 (2.11)			
Week 10 chg	110	-3.0 (2.28)	-2.91 (0.18)	103	-3.7 (1.94)	-3.69 (0.19)	-0.78 (-1.29, -0.26) [-0.37 (-0.64, -0.10)]	0.003
Week 11	112	4.3 (2.32)		107	3.6 (2.13)			
Week 11 chg	112	-3.2 (2.30)	-3.13 (0.18)	107	-3.7 (1.98)	-3.74 (0.19)	-0.60 (-1.12, -0.09) [-0.28 (-0.55, -0.01)]	0.022
Week 12	109	4.3 (2.33)		103	3.5 (2.09)			
Week 12 chg	109	-3.1 (2.31)	-3.04 (0.18)	103	-3.8 (2.10)	-3.81 (0.19)	-0.77 (-1.29, -0.25) [-0.35 (-0.62, -0.08)]	0.004
Week 13	103	4.2 (2.30)		103	3.4 (2.15)			
Week 13 chg	103	-3.3 (2.19)	-3.15 (0.19)	103	-3.9 (2.17)	-3.86 (0.19)	-0.70 (-1.22, -0.19) [-0.32 (-0.60, -0.05)]	0.008
Week 14	109	4.2 (2.35)		107	3.5 (2.14)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2155
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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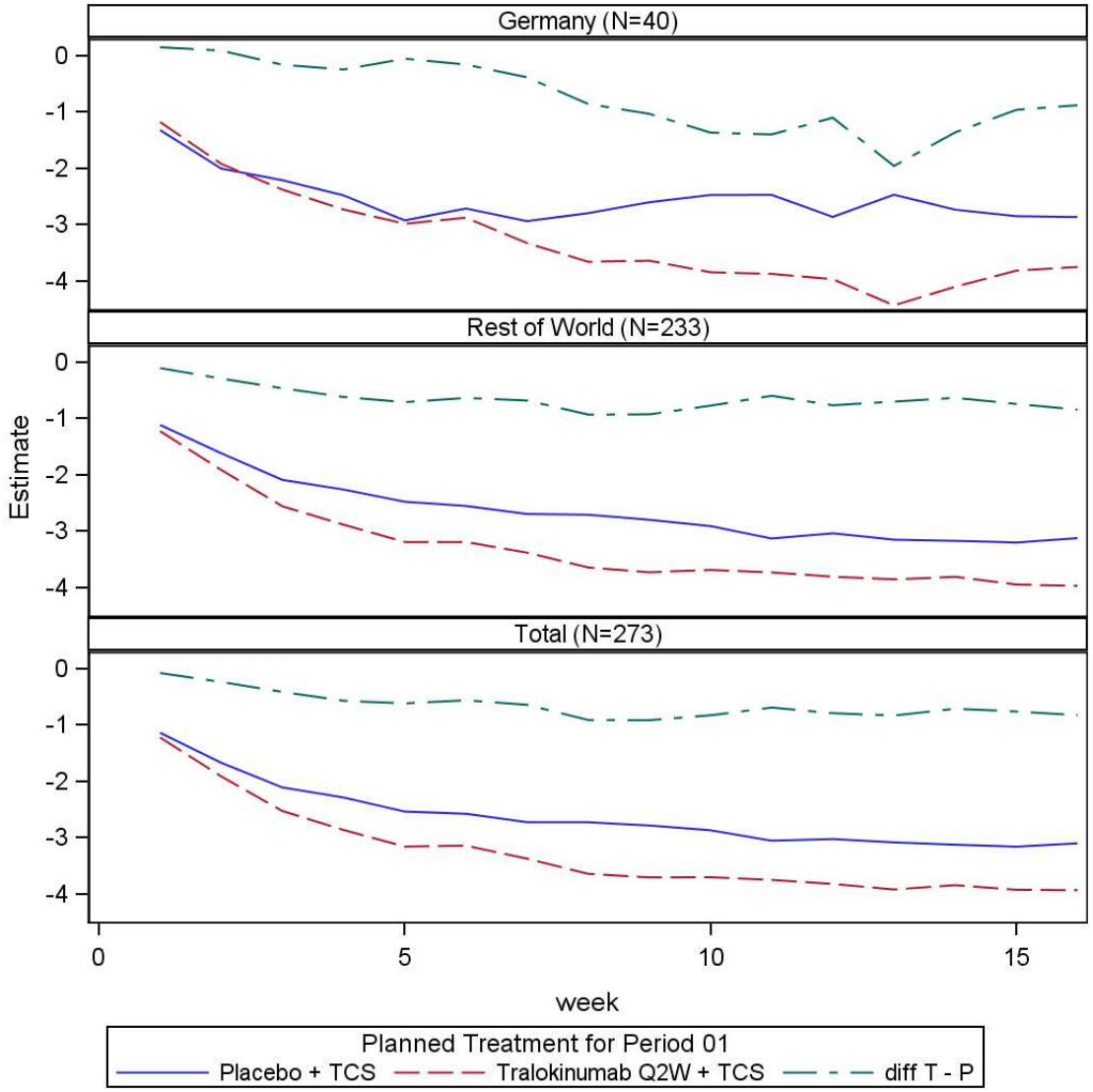
Table 1.16.403.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	-3.3 (2.24)	-3.17 (0.18)	107	-3.8 (2.20)	-3.81 (0.19)	-0.64 (-1.15, -0.12) [-0.29 (-0.56, -0.02)]	0.015
Week 15	107	4.2 (2.25)		106	3.4 (2.12)			
Week 15 chg	107	-3.4 (2.24)	-3.20 (0.18)	106	-4.0 (2.18)	-3.95 (0.19)	-0.75 (-1.26, -0.23) [-0.34 (-0.61, -0.07)]	0.005
Week 16	107	4.2 (2.23)		105	3.4 (2.05)			
Week 16 chg	107	-3.3 (2.23)	-3.13 (0.18)	105	-3.9 (2.09)	-3.97 (0.19)	-0.85 (-1.36, -0.33) [-0.39 (-0.66, -0.12)]	0.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2155
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.403.4.2: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.16.405.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 1		135 5.8 (2.01)			136 5.2 (2.21)		
Week 1 chg		135 -1.1 (1.50)	-1.07 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.08 (-0.58, 0.42) 0.756 [-0.05 (-0.29, 0.18)]
Week 2		134 5.2 (2.29)			132 4.5 (2.45)		
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.18)	-0.18 (-0.68, 0.33) 0.493 [-0.09 (-0.33, 0.15)]
Week 3		133 4.7 (2.36)			131 3.9 (2.35)		
Week 3 chg		133 -2.2 (2.17)	-2.13 (0.18)		131 -2.4 (2.01)	-2.49 (0.18)	-0.36 (-0.86, 0.14) 0.160 [-0.17 (-0.41, 0.07)]
Week 4		130 4.5 (2.48)			133 3.6 (2.39)		
Week 4 chg		130 -2.4 (2.23)	-2.26 (0.18)		133 -2.7 (2.06)	-2.79 (0.18)	-0.53 (-1.03, -0.03) 0.038 [-0.25 (-0.49, -0.01)]
Week 5		131 4.2 (2.55)			129 3.3 (2.42)		
Week 5 chg		131 -2.7 (2.37)	-2.56 (0.18)		129 -3.0 (2.16)	-3.14 (0.18)	-0.58 (-1.08, -0.07) 0.024 [-0.25 (-0.50, -0.01)]
Week 6		130 4.2 (2.52)			129 3.3 (2.42)		
Week 6 chg		130 -2.7 (2.36)	-2.53 (0.18)		129 -3.1 (2.24)	-3.20 (0.18)	-0.67 (-1.17, -0.17) 0.009 [-0.29 (-0.54, -0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.405.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	3.9 (2.43)		128	3.1 (2.37)			
Week 7 chg	129	-3.0 (2.38)	-2.81 (0.18)	128	-3.3 (2.28)	-3.41 (0.18)	-0.60 (-1.10, -0.10) [-0.26 (-0.50, -0.01)]	0.020
Week 8	127	3.9 (2.46)		125	2.8 (2.29)			
Week 8 chg	127	-3.0 (2.32)	-2.79 (0.18)	125	-3.6 (2.26)	-3.65 (0.18)	-0.86 (-1.36, -0.35) [-0.37 (-0.62, -0.12)]	<.001
Week 9	127	3.8 (2.49)		127	2.6 (2.22)			
Week 9 chg	127	-3.1 (2.33)	-2.92 (0.18)	127	-3.7 (2.23)	-3.83 (0.18)	-0.91 (-1.41, -0.40) [-0.40 (-0.65, -0.15)]	<.001
Week 10	125	3.7 (2.54)		122	2.7 (2.29)			
Week 10 chg	125	-3.2 (2.40)	-3.04 (0.18)	122	-3.7 (2.29)	-3.82 (0.18)	-0.79 (-1.29, -0.28) [-0.33 (-0.59, -0.08)]	0.002
Week 11	128	3.6 (2.46)		126	2.6 (2.22)			
Week 11 chg	128	-3.3 (2.40)	-3.15 (0.18)	126	-3.8 (2.26)	-3.89 (0.18)	-0.75 (-1.25, -0.24) [-0.32 (-0.57, -0.07)]	0.004
Week 12	123	3.5 (2.44)		121	2.5 (2.21)			
Week 12 chg	123	-3.4 (2.45)	-3.18 (0.18)	121	-3.8 (2.38)	-4.01 (0.18)	-0.82 (-1.33, -0.31) [-0.34 (-0.59, -0.09)]	0.002
Week 13	116	3.4 (2.40)		120	2.3 (2.13)			
Week 13 chg	116	-3.6 (2.32)	-3.32 (0.18)	120	-3.9 (2.26)	-4.05 (0.18)	-0.74 (-1.25, -0.23) [-0.32 (-0.58, -0.06)]	0.005

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.405.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	3.3 (2.42)		123	2.4 (2.18)			
Week 14 chg	123	-3.5 (2.33)	-3.36 (0.18)	123	-3.9 (2.27)	-4.03 (0.18)	-0.67 (-1.18, -0.16) [-0.29 (-0.54, -0.04)]	0.010
Week 15	123	3.3 (2.47)		123	2.4 (2.18)			
Week 15 chg	123	-3.7 (2.35)	-3.42 (0.18)	123	-3.9 (2.35)	-4.08 (0.18)	-0.66 (-1.16, -0.15) [-0.28 (-0.53, -0.03)]	0.011
Week 16	121	3.2 (2.40)		122	2.5 (2.17)			
Week 16 chg	121	-3.7 (2.28)	-3.41 (0.18)	122	-3.9 (2.32)	-4.06 (0.18)	-0.65 (-1.16, -0.14) [-0.28 (-0.54, -0.03)]	0.012

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.405.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Germany												
Baseline	18	18	7.3 (1.71)			22	22	6.1 (1.80)				
Week 1		18	6.0 (2.07)				21	4.8 (2.29)				
Week 1 chg		18	-1.4 (1.63)	-1.27	(0.56)		21	-1.4 (1.42)	-1.41	(0.51)	-0.13 (-1.70, 1.43) [-0.09 (-0.72, 0.54)]	0.864
Week 2		18	5.1 (2.65)				21	4.4 (2.15)				
Week 2 chg		18	-2.2 (2.38)	-2.08	(0.56)		21	-1.7 (1.30)	-1.89	(0.51)	0.19 (-1.38, 1.77) [0.10 (-0.53, 0.73)]	0.805
Week 3		17	4.6 (2.73)				21	3.7 (2.26)				
Week 3 chg		17	-2.7 (2.76)	-2.37	(0.57)		21	-2.3 (1.56)	-2.64	(0.51)	-0.27 (-1.84, 1.31) [-0.12 (-0.76, 0.52)]	0.738
Week 4		17	4.6 (3.17)				21	3.4 (2.18)				
Week 4 chg		17	-2.8 (2.65)	-2.46	(0.57)		21	-2.7 (1.84)	-2.93	(0.51)	-0.47 (-2.04, 1.11) [-0.21 (-0.85, 0.43)]	0.557
Week 5		17	4.1 (3.11)				22	2.8 (2.21)				
Week 5 chg		17	-3.2 (2.84)	-2.87	(0.57)		22	-3.3 (1.99)	-3.46	(0.51)	-0.58 (-2.16, 0.99) [-0.24 (-0.88, 0.39)]	0.459
Week 6		17	4.1 (3.09)				20	3.1 (2.42)				
Week 6 chg		17	-3.2 (2.76)	-2.89	(0.57)		20	-2.8 (1.98)	-3.20	(0.51)	-0.31 (-1.90, 1.27) [-0.13 (-0.78, 0.52)]	0.695
Week 7		17	3.7 (2.98)				20	2.8 (2.37)				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.405.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg		17	-3.6 (2.80)	-3.26	(0.57)		20	-3.4 (2.10)	-3.75	(0.51)	-0.50 (-2.07, 1.08) [-0.20 (-0.85, 0.45)]	0.531
Week 8		17	3.9 (3.13)				20	2.4 (2.40)				
Week 8 chg		17	-3.4 (2.84)	-3.08	(0.57)		20	-3.8 (2.24)	-4.05	(0.51)	-0.98 (-2.56, 0.60) [-0.39 (-1.04, 0.27)]	0.219
Week 9		16	4.2 (3.04)				20	2.3 (1.84)				
Week 9 chg		16	-3.1 (2.76)	-2.87	(0.57)		20	-4.0 (2.05)	-4.07	(0.51)	-1.20 (-2.78, 0.38) [-0.50 (-1.17, 0.17)]	0.135
Week 10		15	4.6 (3.13)				19	2.0 (2.02)				
Week 10 chg		15	-2.8 (2.85)	-2.76	(0.57)		19	-4.2 (2.10)	-4.45	(0.51)	-1.69 (-3.29, -0.10) [-0.69 (-1.38, 0.01)]	0.038
Week 11		16	4.3 (3.03)				19	2.0 (2.02)				
Week 11 chg		16	-3.1 (2.77)	-2.82	(0.57)		19	-4.2 (2.11)	-4.45	(0.51)	-1.63 (-3.21, -0.04) [-0.67 (-1.35, 0.01)]	0.044
Week 12		14	3.5 (2.77)				18	2.1 (1.85)				
Week 12 chg		14	-3.6 (2.95)	-3.17	(0.58)		18	-4.0 (2.12)	-4.42	(0.52)	-1.25 (-2.85, 0.35) [-0.50 (-1.21, 0.21)]	0.122
Week 13		13	3.9 (2.78)				17	1.6 (1.36)				
Week 13 chg		13	-3.3 (2.89)	-2.98	(0.58)		17	-4.5 (1.95)	-4.79	(0.52)	-1.81 (-3.42, -0.20) [-0.75 (-1.50, -0.01)]	0.028
Week 14		14	4.1 (2.69)				16	1.6 (1.59)				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.405.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	14	-3.2 (2.82)	-2.94 (0.58)	16	-4.7 (1.83)	-4.71 (0.52)	-1.77 (-3.38, -0.16) 0.032 [-0.76 (-1.50, -0.01)]
Week 15	16	3.8 (3.22)		17	1.9 (1.60)		
Week 15 chg	16	-3.6 (3.04)	-3.18 (0.57)	17	-4.2 (2.22)	-4.54 (0.52)	-1.36 (-2.96, 0.24) 0.094 [-0.51 (-1.21, 0.18)]
Week 16	14	3.4 (2.94)		17	1.9 (1.85)		
Week 16 chg	14	-4.0 (2.91)	-3.36 (0.58)	17	-4.2 (2.18)	-4.52 (0.52)	-1.16 (-2.77, 0.45) 0.155 [-0.46 (-1.17, 0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.405.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	118 6.8 (1.63)		116	115 6.3 (2.17)		
Week 1		117 5.8 (2.01)			115 5.3 (2.19)		
Week 1 chg		117 -1.1 (1.48)	-1.04 (0.19)		115 -1.1 (1.46)	-1.10 (0.19)	-0.05 (-0.59, 0.48) 0.844 [-0.04 (-0.29, 0.22)]
Week 2		116 5.2 (2.24)			111 4.6 (2.52)		
Week 2 chg		116 -1.7 (1.92)	-1.61 (0.19)		111 -1.8 (1.89)	-1.84 (0.19)	-0.23 (-0.76, 0.31) 0.405 [-0.12 (-0.38, 0.14)]
Week 3		116 4.7 (2.31)			110 3.9 (2.37)		
Week 3 chg		116 -2.2 (2.08)	-2.09 (0.19)		110 -2.4 (2.09)	-2.46 (0.19)	-0.37 (-0.90, 0.17) 0.175 [-0.18 (-0.44, 0.08)]
Week 4		113 4.5 (2.38)			112 3.7 (2.43)		
Week 4 chg		113 -2.3 (2.16)	-2.23 (0.19)		112 -2.7 (2.11)	-2.76 (0.19)	-0.53 (-1.06, 0.01) 0.054 [-0.25 (-0.51, 0.02)]
Week 5		114 4.2 (2.47)			107 3.4 (2.46)		
Week 5 chg		114 -2.6 (2.29)	-2.51 (0.19)		107 -3.0 (2.20)	-3.07 (0.19)	-0.56 (-1.10, -0.03) 0.040 [-0.25 (-0.51, 0.02)]
Week 6		113 4.2 (2.44)			109 3.3 (2.43)		
Week 6 chg		113 -2.6 (2.29)	-2.49 (0.19)		109 -3.1 (2.29)	-3.19 (0.19)	-0.70 (-1.24, -0.17) 0.010 [-0.31 (-0.57, -0.04)]
Week 7		112 3.9 (2.35)			108 3.1 (2.37)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.405.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	112	-2.9 (2.31)	-2.75 (0.19)	108	-3.3 (2.32)	-3.34 (0.19)	-0.59 (-1.13, -0.06) [-0.26 (-0.52, 0.01)]	0.031
Week 8	110	3.9 (2.36)		105	2.9 (2.27)			
Week 8 chg	110	-2.9 (2.23)	-2.76 (0.19)	105	-3.5 (2.28)	-3.57 (0.19)	-0.81 (-1.35, -0.27) [-0.36 (-0.63, -0.09)]	0.003
Week 9	111	3.8 (2.41)		107	2.7 (2.28)			
Week 9 chg	111	-3.1 (2.28)	-2.93 (0.19)	107	-3.7 (2.27)	-3.79 (0.19)	-0.86 (-1.40, -0.32) [-0.38 (-0.65, -0.11)]	0.002
Week 10	110	3.6 (2.44)		103	2.8 (2.33)			
Week 10 chg	110	-3.3 (2.34)	-3.07 (0.19)	103	-3.6 (2.32)	-3.70 (0.19)	-0.64 (-1.17, -0.10) [-0.27 (-0.54, -0.00)]	0.021
Week 11	112	3.5 (2.37)		107	2.7 (2.24)			
Week 11 chg	112	-3.3 (2.35)	-3.19 (0.19)	107	-3.7 (2.29)	-3.79 (0.19)	-0.60 (-1.14, -0.07) [-0.26 (-0.53, 0.01)]	0.028
Week 12	109	3.5 (2.41)		103	2.6 (2.27)			
Week 12 chg	109	-3.3 (2.40)	-3.18 (0.19)	103	-3.8 (2.43)	-3.94 (0.19)	-0.76 (-1.29, -0.22) [-0.31 (-0.58, -0.04)]	0.006
Week 13	103	3.3 (2.36)		103	2.4 (2.21)			
Week 13 chg	103	-3.6 (2.26)	-3.35 (0.19)	103	-3.9 (2.31)	-3.93 (0.19)	-0.58 (-1.13, -0.04) [-0.26 (-0.53, 0.02)]	0.035
Week 14	109	3.3 (2.38)		107	2.5 (2.24)			

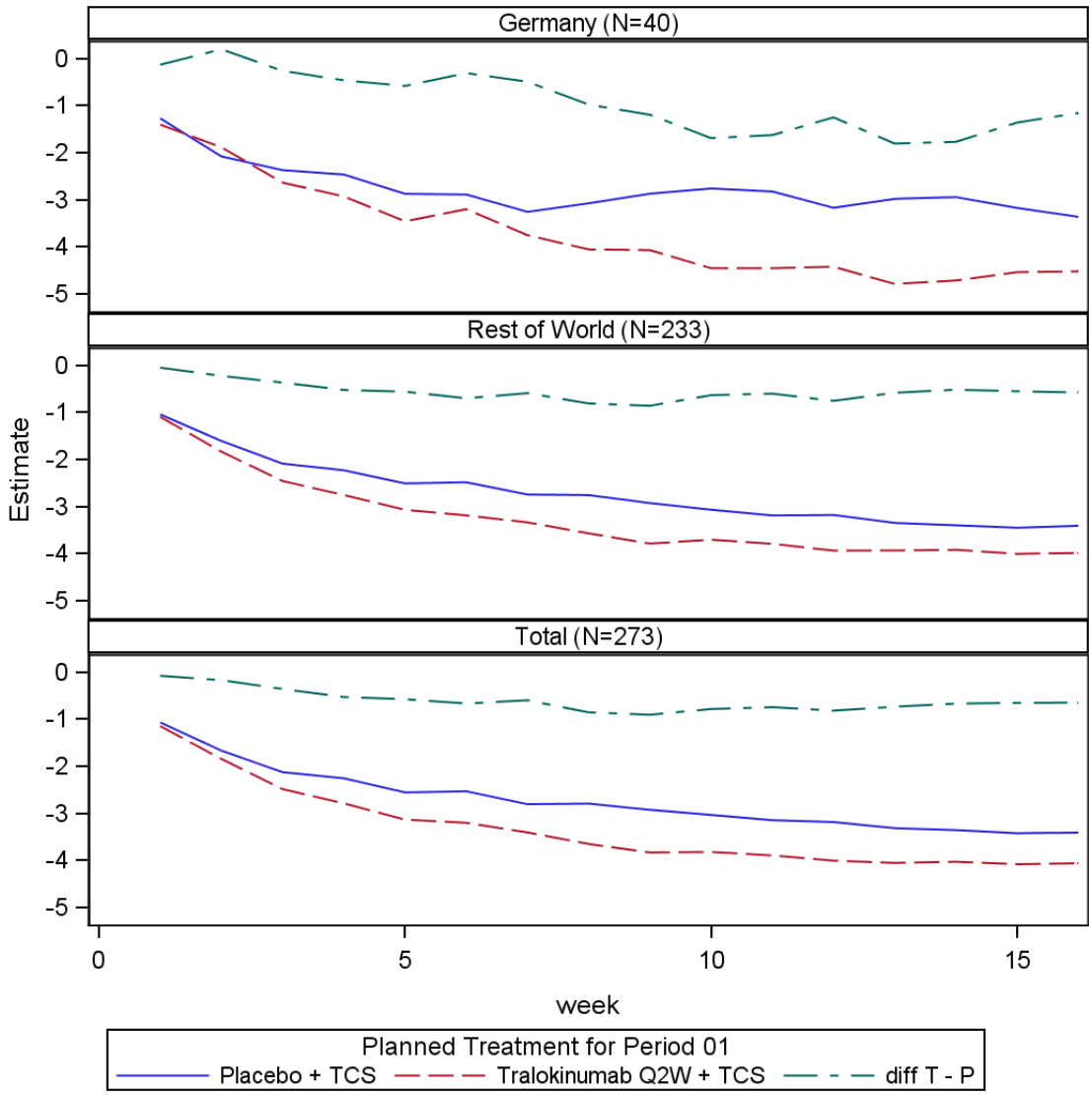
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.405.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	-3.6 (2.27)	-3.40 (0.19)	107	-3.8 (2.31)	-3.92 (0.19)	-0.52 (-1.06, 0.02) [-0.23 (-0.49, 0.04)]	0.058
Week 15	107	3.2 (2.35)		106	2.5 (2.25)			
Week 15 chg	107	-3.7 (2.25)	-3.45 (0.19)	106	-3.9 (2.37)	-4.00 (0.19)	-0.55 (-1.09, -0.01) [-0.24 (-0.51, 0.03)]	0.044
Week 16	107	3.2 (2.33)		105	2.5 (2.21)			
Week 16 chg	107	-3.7 (2.19)	-3.41 (0.19)	105	-3.8 (2.35)	-3.98 (0.19)	-0.58 (-1.12, -0.04) [-0.25 (-0.52, 0.02)]	0.036

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3533
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.405.4.2: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.16.407.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.22 (1.49)		138 -20.9 (16.72)	-21.06 (1.48)	-3.84 (-7.97, 0.30) 0.069 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.25 (1.50)		137 -30.8 (17.25)	-31.00 (1.49)	-4.75 (-8.90, -0.60) 0.025 [-0.27 (-0.51, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.77 (1.50)		134 -34.3 (17.49)	-34.45 (1.49)	-7.67 (-11.8, -3.51) <.001 [-0.42 (-0.66, -0.18)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.63 (1.50)		130 -36.6 (18.48)	-36.80 (1.50)	-8.16 (-12.3, -3.99) <.001 [-0.43 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.78 (1.50)		130 -38.5 (19.49)	-38.59 (1.50)	-7.81 (-12.0, -3.63) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.51 (1.51)		128 -39.5 (18.74)	-39.57 (1.51)	-8.06 (-12.3, -3.87) <.001 [-0.42 (-0.67, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9761
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.407.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	36.0 (19.61)		127	28.3 (17.87)		
Week 14 chg	126	-34.8 (20.31)	-34.13 (1.52)	127	-41.8 (20.11)	-41.35 (1.51)	-7.22 (-11.4, -3.01) <.001 [-0.36 (-0.61, -0.11)]
Week 16	124	36.3 (18.78)		123	27.0 (16.90)		
Week 16 chg	124	-34.7 (19.94)	-33.86 (1.52)	123	-43.3 (19.46)	-42.65 (1.52)	-8.79 (-13.0, -4.57) <.001 [-0.45 (-0.70, -0.19)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9761
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.407.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 69.5 (9.23)		22	22 67.2 (6.09)		
Week 2		18 51.9 (14.71)			22 47.3 (12.97)		
Week 2 chg		18 -17.5 (16.40)	-16.62 (3.97)		22 -19.9 (12.07)	-20.55 (3.58)	-3.93 (-14.7, 6.84) 0.469 [-0.28 (-0.90, 0.35)]
Week 4		17 40.7 (17.64)			22 39.0 (14.92)		
Week 4 chg		17 -29.0 (19.85)	-26.91 (4.04)		22 -28.2 (15.45)	-29.13 (3.58)	-2.22 (-13.1, 8.65) 0.685 [-0.13 (-0.76, 0.51)]
Week 6		17 40.9 (21.12)			22 35.6 (14.66)		
Week 6 chg		17 -28.8 (20.82)	-27.24 (4.04)		22 -31.6 (15.37)	-32.22 (3.58)	-4.98 (-15.9, 5.90) 0.364 [-0.28 (-0.91, 0.36)]
Week 8		17 41.8 (21.74)			20 30.5 (11.77)		
Week 8 chg		17 -28.0 (22.06)	-26.07 (4.04)		20 -36.1 (13.71)	-36.81 (3.67)	-10.74 (-21.7, 0.26) 0.056 [-0.60 (-1.26, 0.06)]
Week 10		17 38.6 (21.01)			20 28.9 (12.79)		
Week 10 chg		17 -31.2 (21.41)	-29.42 (4.04)		20 -37.6 (13.89)	-38.23 (3.67)	-8.81 (-19.8, 2.20) 0.115 [-0.50 (-1.15, 0.16)]
Week 12		16 38.7 (22.41)			19 28.4 (17.09)		
Week 12 chg		16 -31.4 (22.26)	-27.99 (4.10)		19 -38.0 (18.55)	-38.98 (3.71)	-10.99 (-22.1, 0.15) 0.053 [-0.54 (-1.22, 0.14)]
Week 14		17 38.5 (22.59)			19 27.3 (10.89)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9761
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 15:55 LP0162-Payer /p_mmrm3/t_t_reg3_g07_46_w16.txt

Table 1.16.407.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	17	-31.2 (22.25)	-29.46 (4.04)	19	-39.3 (13.44)	-38.66 (3.71)	-9.20 (-20.3, 1.85) [-0.51 (-1.17, 0.16)]	0.101
Week 16	17	36.6 (23.16)		19	24.9 (9.31)			
Week 16 chg	17	-33.1 (22.89)	-31.45 (4.04)	19	-41.6 (11.31)	-40.91 (3.71)	-9.46 (-20.5, 1.59) [-0.53 (-1.20, 0.13)]	0.092

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9761
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.407.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 71.0 (13.32)		116	116 70.7 (12.81)		
Week 2		119 53.6 (18.06)			116 49.7 (19.04)		
Week 2 chg		119 -17.5 (16.08)	-17.25 (1.62)		116 -21.1 (17.50)	-21.21 (1.64)	-3.96 (-8.49, 0.57) 0.086 [-0.24 (-0.49, 0.02)]
Week 4		117 44.3 (18.47)			115 39.2 (18.17)		
Week 4 chg		117 -26.6 (18.30)	-26.06 (1.62)		115 -31.3 (17.59)	-31.43 (1.64)	-5.37 (-9.91, -0.83) 0.021 [-0.30 (-0.56, -0.04)]
Week 6		115 43.8 (18.65)			112 35.8 (17.06)		
Week 6 chg		115 -27.2 (18.98)	-26.71 (1.63)		112 -34.8 (17.89)	-34.88 (1.65)	-8.18 (-12.7, -3.61) <.001 [-0.44 (-0.71, -0.18)]
Week 8		116 41.5 (19.93)			110 33.9 (17.75)		
Week 8 chg		116 -29.2 (19.65)	-28.97 (1.63)		110 -36.7 (19.27)	-36.85 (1.66)	-7.88 (-12.4, -3.31) <.001 [-0.40 (-0.67, -0.14)]
Week 10		114 39.4 (19.88)			110 31.9 (19.02)		
Week 10 chg		114 -31.6 (21.17)	-30.98 (1.63)		110 -38.7 (20.38)	-38.66 (1.66)	-7.68 (-12.3, -3.10) 0.001 [-0.37 (-0.63, -0.11)]
Week 12		112 38.6 (17.67)			109 30.8 (17.81)		
Week 12 chg		112 -32.6 (19.35)	-32.01 (1.64)		109 -39.8 (18.85)	-39.71 (1.66)	-7.70 (-12.3, -3.11) 0.001 [-0.40 (-0.67, -0.14)]
Week 14		109 35.6 (19.19)			108 28.5 (18.87)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9761
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

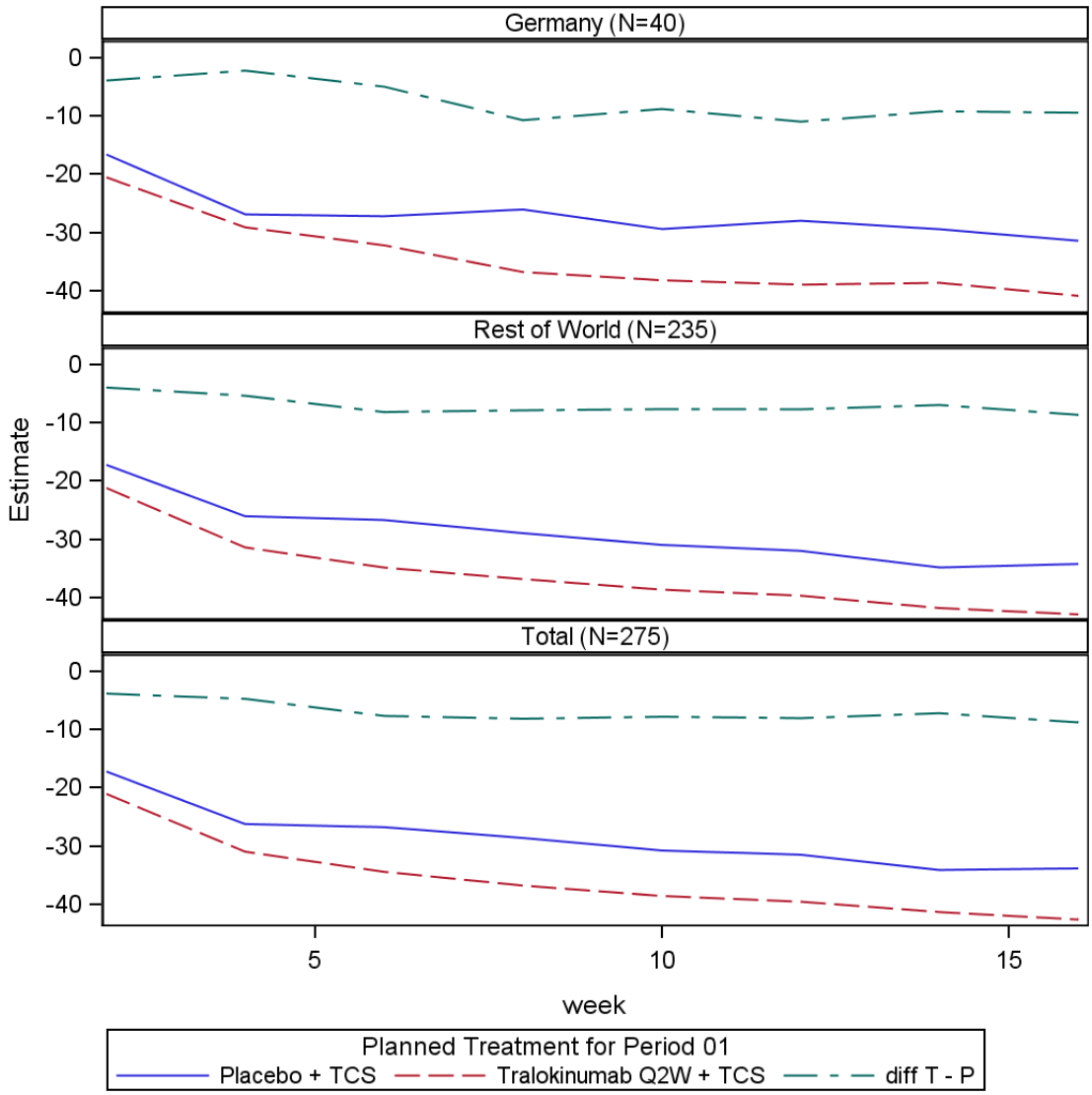
12MAY21 15:55 LP0162-Payer /p_mmrm3/t_t_reg3_g07_46_w16.txt

Table 1.16.407.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	-35.3 (20.05)	-34.87 (1.65)	108	-42.2 (21.09)	-41.82 (1.66)	-6.96 (-11.6, -2.36) [-0.34 (-0.61, -0.07)]	0.003
Week 16	107	36.3 (18.11)		104	27.3 (17.95)			
Week 16 chg	107	-35.0 (19.53)	-34.26 (1.65)	104	-43.6 (20.63)	-42.92 (1.67)	-8.66 (-13.3, -4.03) [-0.43 (-0.70, -0.16)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9761
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.407.4.2: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.16.409.4.1: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score											
Total											
Baseline	137	134	16.4 (6.33)			138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)				132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.15 (0.45)			132	-7.5 (5.92)	-7.56 (0.45)		-0.41 (-1.65, 0.84) 0.520 [-0.07 (-0.31, 0.17)]
Week 4		130	7.8 (6.27)				135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.32 (0.45)			135	-9.0 (6.32)	-9.14 (0.44)		-0.82 (-2.06, 0.42) 0.196 [-0.13 (-0.37, 0.12)]
Week 6		123	7.3 (6.07)				126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.65 (0.45)			126	-10.0 (6.75)	-9.87 (0.45)		-1.22 (-2.48, 0.03) 0.056 [-0.18 (-0.42, 0.07)]
Week 8		127	6.9 (5.70)				128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.97 (0.45)			128	-10.6 (6.29)	-10.39 (0.45)		-1.42 (-2.67, -0.17) 0.026 [-0.22 (-0.46, 0.03)]
Week 12		123	6.8 (5.89)				124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.30 (0.46)			124	-10.6 (5.77)	-10.58 (0.45)		-1.28 (-2.54, -0.02) 0.046 [-0.20 (-0.45, 0.05)]
Week 16		120	6.5 (5.63)				118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.46)			118	-11.0 (5.99)	-11.18 (0.46)		-1.50 (-2.77, -0.23) 0.021 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5737
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.409.4.1: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany											
Baseline	18	17	16.0 (7.96)			22	22	16.1 (5.18)			
Week 2		16	9.3 (6.18)				21	9.0 (5.02)			
Week 2 chg		16	-7.4 (8.28)	-7.31	(1.38)		21	-7.2 (4.47)	-7.28	(1.21)	0.04 (-3.67, 3.74) 0.985 [0.01 (-0.64, 0.66)]
Week 4		16	7.6 (5.27)				21	5.5 (5.35)			
Week 4 chg		16	-8.4 (8.82)	-7.93	(1.39)		21	-10.4 (5.34)	-10.52	(1.21)	-2.59 (-6.30, 1.12) 0.166 [-0.37 (-1.02, 0.29)]
Week 6		15	7.4 (6.08)				22	7.0 (7.08)			
Week 6 chg		15	-9.3 (8.56)	-8.42	(1.40)		22	-9.0 (7.32)	-9.10	(1.21)	-0.69 (-4.40, 3.03) 0.713 [-0.09 (-0.74, 0.57)]
Week 8		16	6.9 (4.64)				20	5.6 (6.46)			
Week 8 chg		16	-9.0 (8.49)	-8.55	(1.39)		20	-10.7 (6.25)	-10.19	(1.22)	-1.64 (-5.36, 2.09) 0.382 [-0.22 (-0.88, 0.44)]
Week 12		15	6.4 (4.64)				19	5.2 (4.21)			
Week 12 chg		15	-9.9 (8.48)	-9.11	(1.40)		19	-11.3 (5.79)	-10.61	(1.23)	-1.50 (-5.25, 2.25) 0.427 [-0.21 (-0.89, 0.47)]
Week 16		16	6.9 (5.94)				19	5.0 (5.17)			
Week 16 chg		16	-9.0 (8.91)	-8.56	(1.39)		19	-11.0 (5.79)	-10.50	(1.23)	-1.94 (-5.67, 1.79) 0.301 [-0.26 (-0.93, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5737
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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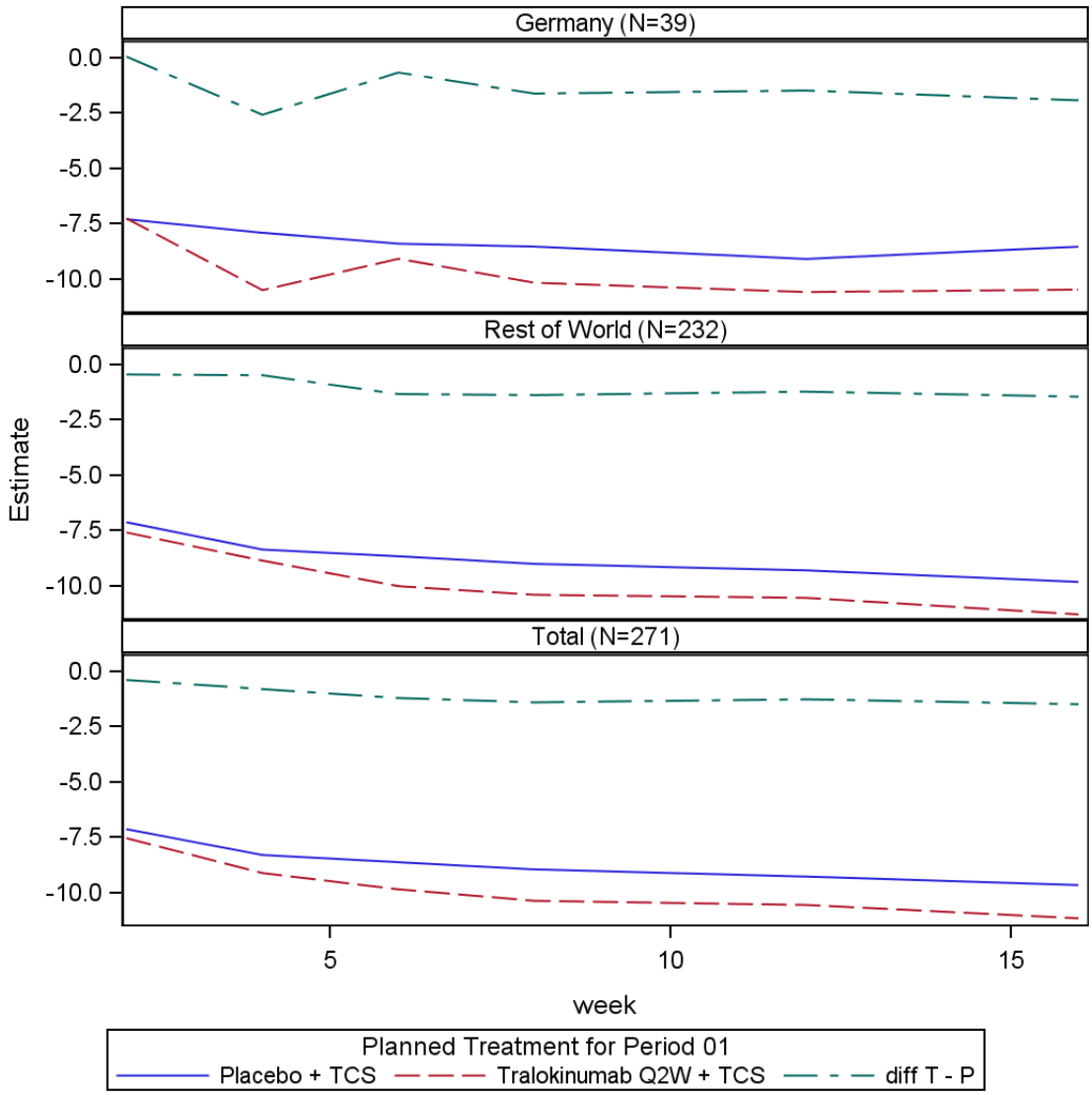
Table 1.16.409.4.1: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	117	16.4 (6.10)			116	115	15.8 (6.78)			
Week 2		115	9.2 (6.54)				111	8.4 (6.38)			
Week 2 chg		115	-7.2 (5.33)	-7.14	(0.48)		111	-7.6 (6.17)	-7.61	(0.48)	-0.46 (-1.80, 0.87) 0.495 [-0.08 (-0.34, 0.18)]
Week 4		114	7.8 (6.42)				114	7.0 (6.09)			
Week 4 chg		114	-8.6 (6.36)	-8.38	(0.48)		114	-8.8 (6.47)	-8.88	(0.48)	-0.50 (-1.83, 0.83) 0.461 [-0.08 (-0.34, 0.18)]
Week 6		108	7.3 (6.10)				104	5.8 (5.50)			
Week 6 chg		108	-8.9 (7.08)	-8.68	(0.48)		104	-10.2 (6.64)	-10.03	(0.49)	-1.35 (-2.70, 0.00) 0.050 [-0.20 (-0.47, 0.07)]
Week 8		111	6.9 (5.86)				108	5.4 (4.86)			
Week 8 chg		111	-9.4 (6.61)	-9.03	(0.48)		108	-10.6 (6.33)	-10.42	(0.49)	-1.40 (-2.74, -0.05) 0.042 [-0.22 (-0.48, 0.05)]
Week 12		108	6.8 (6.06)				105	5.0 (3.89)			
Week 12 chg		108	-9.8 (7.12)	-9.32	(0.48)		105	-10.5 (5.78)	-10.56	(0.49)	-1.24 (-2.60, 0.11) 0.072 [-0.19 (-0.46, 0.08)]
Week 16		104	6.4 (5.61)				99	4.4 (3.60)			
Week 16 chg		104	-10.1 (6.14)	-9.84	(0.49)		99	-10.9 (6.06)	-11.31	(0.50)	-1.47 (-2.84, -0.10) 0.035 [-0.24 (-0.52, 0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5737
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.409.4.2: Total, Region, change in DLQI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.16.410.4.1: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total									
Total									
Baseline	137	134	20.9 (5.72)		138	135	21.3 (5.12)		
Week 2		130	15.1 (6.91)			130	13.5 (6.31)		
Week 2 chg		130	-5.9 (6.29)	-5.98 (0.55)		130	-7.7 (5.43)	-7.66 (0.54)	-1.69 (-3.20, -0.17) 0.029 [-0.29 (-0.53, -0.04)]
Week 4		130	13.8 (7.45)			133	11.6 (6.30)		
Week 4 chg		130	-7.1 (7.56)	-7.12 (0.55)		133	-9.7 (6.02)	-9.53 (0.54)	-2.40 (-3.92, -0.89) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123	13.5 (7.81)			124	10.9 (5.95)		
Week 6 chg		123	-7.2 (8.29)	-7.34 (0.55)		124	-10.6 (6.27)	-10.36 (0.55)	-3.02 (-4.56, -1.48) <.001 [-0.41 (-0.66, -0.16)]
Week 8		127	13.1 (7.02)			126	9.9 (5.79)		
Week 8 chg		127	-7.6 (7.95)	-7.73 (0.55)		126	-11.5 (6.10)	-11.20 (0.55)	-3.47 (-5.00, -1.94) <.001 [-0.49 (-0.74, -0.24)]
Week 12		123	13.0 (7.39)			122	9.2 (5.72)		
Week 12 chg		123	-8.0 (8.26)	-7.90 (0.55)		122	-12.4 (6.20)	-11.83 (0.55)	-3.93 (-5.47, -2.39) <.001 [-0.54 (-0.79, -0.28)]
Week 16		120	13.0 (7.69)			116	9.1 (5.58)		
Week 16 chg		120	-8.0 (8.09)	-8.05 (0.56)		116	-12.2 (6.39)	-11.87 (0.56)	-3.82 (-5.37, -2.27) <.001 [-0.52 (-0.78, -0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5103
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 16:07 LP0162-Payer /p_mmrm3/t_t_reg3_g10_46_w16.txt

Table 1.16.410.4.1: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 21.5 (6.18)		22	22 22.5 (4.35)		
Week 2		16 17.0 (7.11)			21 15.2 (5.79)		
Week 2 chg		16 -5.1 (7.32)	-5.06 (1.62)		21 -7.4 (4.35)	-7.30 (1.42)	-2.24 (-6.56, 2.08) 0.303 [-0.39 (-1.04, 0.27)]
Week 4		16 15.8 (8.70)			21 11.7 (5.36)		
Week 4 chg		16 -5.5 (8.07)	-5.73 (1.64)		21 -10.5 (6.04)	-10.22 (1.42)	-4.49 (-8.83, -0.15) 0.043 [-0.64 (-1.31, 0.02)]
Week 6		15 17.3 (8.35)			22 11.8 (6.32)		
Week 6 chg		15 -4.7 (8.57)	-4.57 (1.65)		22 -10.7 (7.19)	-10.42 (1.41)	-5.85 (-10.2, -1.50) 0.009 [-0.75 (-1.43, -0.07)]
Week 8		16 15.7 (8.48)			20 10.2 (5.01)		
Week 8 chg		16 -5.6 (9.10)	-6.02 (1.64)		20 -12.3 (6.10)	-11.70 (1.44)	-5.68 (-10.0, -1.31) 0.012 [-0.75 (-1.43, -0.07)]
Week 12		15 13.8 (8.43)			19 9.0 (5.35)		
Week 12 chg		15 -7.5 (10.42)	-7.52 (1.66)		19 -13.9 (6.10)	-12.88 (1.46)	-5.36 (-9.79, -0.93) 0.019 [-0.65 (-1.34, 0.05)]
Week 16		16 14.4 (8.20)			19 10.3 (6.34)		
Week 16 chg		16 -6.9 (8.93)	-7.33 (1.64)		19 -11.9 (7.29)	-11.13 (1.45)	-3.80 (-8.19, 0.58) 0.088 [-0.47 (-1.15, 0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5103
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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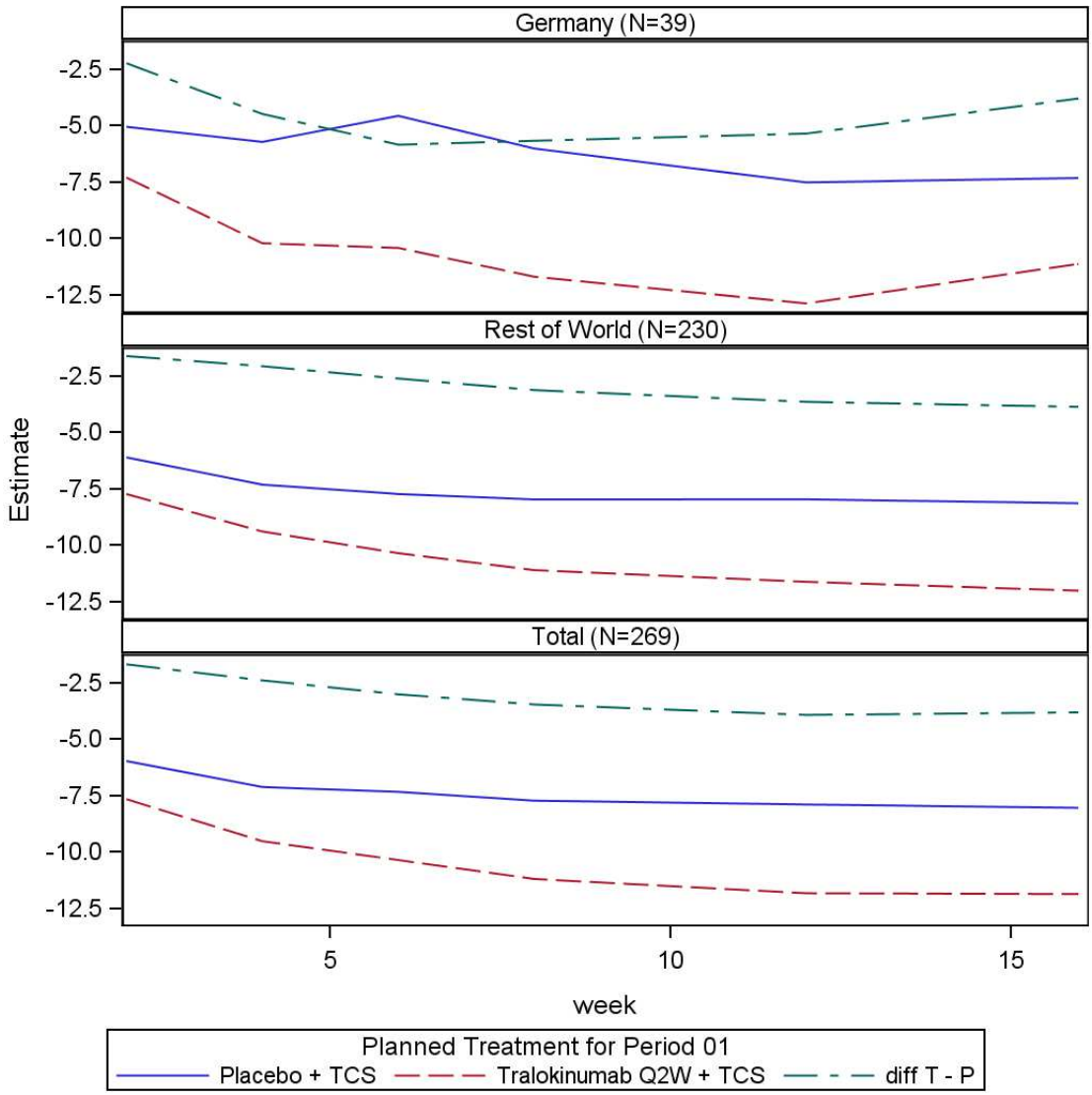
Table 1.16.410.4.1: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World												
Baseline	119	117	20.8 (5.67)			116	113	21.0 (5.25)				
Week 2		114	14.9 (6.88)				109	13.2 (6.38)				
Week 2 chg		114	-6.0 (6.16)	-6.11	(0.58)		109	-7.8 (5.62)	-7.74	(0.59)	-1.62 (-3.25, 0.00) [-0.28 (-0.54, -0.01)]	0.051
Week 4		114	13.5 (7.26)				112	11.6 (6.49)				
Week 4 chg		114	-7.3 (7.49)	-7.32	(0.58)		112	-9.5 (6.03)	-9.40	(0.59)	-2.07 (-3.70, -0.45) [-0.30 (-0.57, -0.04)]	0.012
Week 6		108	13.0 (7.62)				102	10.7 (5.89)				
Week 6 chg		108	-7.5 (8.23)	-7.74	(0.59)		102	-10.6 (6.09)	-10.36	(0.60)	-2.62 (-4.27, -0.97) [-0.36 (-0.63, -0.09)]	0.002
Week 8		111	12.7 (6.75)				106	9.9 (5.95)				
Week 8 chg		111	-7.9 (7.78)	-7.98	(0.58)		106	-11.4 (6.12)	-11.11	(0.60)	-3.13 (-4.77, -1.49) [-0.45 (-0.72, -0.18)]	<.001
Week 12		108	12.9 (7.27)				103	9.3 (5.81)				
Week 12 chg		108	-8.1 (7.97)	-7.97	(0.59)		103	-12.1 (6.20)	-11.63	(0.60)	-3.65 (-5.30, -2.00) [-0.51 (-0.78, -0.24)]	<.001
Week 16		104	12.8 (7.62)				97	8.8 (5.42)				
Week 16 chg		104	-8.2 (7.99)	-8.14	(0.59)		97	-12.3 (6.24)	-12.02	(0.61)	-3.87 (-5.54, -2.21) [-0.54 (-0.82, -0.26)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5103
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.410.4.2: Total, Region, change in POEM, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.16.414.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.60 (0.81)		138 -12.9 (10.72)	-13.33 (0.81)	-0.73 (-2.98, 1.53) 0.526 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.57 (0.81)		137 -18.8 (10.58)	-19.44 (0.81)	-1.86 (-4.13, 0.40) 0.106 [-0.17 (-0.40, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.53 (0.82)		134 -20.9 (11.93)	-21.51 (0.81)	-2.98 (-5.25, -0.71) 0.010 [-0.24 (-0.48, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.30 (0.82)		130 -22.5 (12.16)	-23.17 (0.82)	-3.88 (-6.15, -1.60) <.001 [-0.30 (-0.54, -0.05)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.61 (0.82)		130 -24.3 (11.55)	-25.02 (0.82)	-4.41 (-6.69, -2.13) <.001 [-0.34 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-21.10 (0.82)		128 -24.7 (12.40)	-25.22 (0.82)	-4.11 (-6.40, -1.83) <.001 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9803
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.414.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	11.2 (11.57)		127	7.0 (8.34)		
Week 14 chg	126	-22.8 (14.69)	-21.89 (0.82)	127	-25.1 (13.29)	-25.74 (0.82)	-3.85 (-6.14, -1.55) 0.001 [-0.27 (-0.52, -0.03)]
Week 16	124	10.5 (11.42)		123	6.4 (7.63)		
Week 16 chg	124	-23.8 (14.93)	-22.65 (0.83)	123	-25.9 (12.78)	-26.17 (0.83)	-3.52 (-5.82, -1.22) 0.003 [-0.25 (-0.50, -0.00)]
Week 18	116	10.7 (11.52)		115	5.9 (7.36)		
Week 18 chg	116	-23.6 (14.71)	-22.56 (0.84)	115	-26.4 (12.11)	-26.14 (0.84)	-3.58 (-5.91, -1.25) 0.003 [-0.27 (-0.52, -0.01)]
Week 20	107	10.6 (12.56)		117	5.5 (6.56)		
Week 20 chg	107	-24.1 (15.32)	-22.56 (0.85)	117	-26.9 (11.94)	-26.74 (0.84)	-4.18 (-6.53, -1.84) <.001 [-0.31 (-0.57, -0.04)]
Week 22	112	10.5 (11.17)		114	5.0 (5.93)		
Week 22 chg	112	-24.3 (14.63)	-22.40 (0.84)	114	-27.3 (12.17)	-27.13 (0.84)	-4.73 (-7.08, -2.39) <.001 [-0.35 (-0.61, -0.09)]
Week 24	112	9.9 (11.00)		117	5.3 (7.21)		
Week 24 chg	112	-24.9 (14.38)	-22.80 (0.84)	117	-27.0 (12.11)	-26.99 (0.84)	-4.19 (-6.53, -1.85) <.001 [-0.32 (-0.58, -0.06)]
Week 26	118	9.1 (10.14)		125	5.6 (7.90)		
Week 26 chg	118	-25.5 (13.74)	-23.71 (0.83)	125	-26.5 (12.83)	-27.01 (0.82)	-3.30 (-5.61, -0.99) 0.005 [-0.25 (-0.50, 0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9803
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.414.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 28.6 (7.70)		22	22 28.9 (7.99)		
Week 2		18 16.9 (10.44)			22 17.1 (10.70)		
Week 2 chg		18 -11.7 (9.36)	-11.63 (2.03)		22 -11.8 (5.57)	-11.79 (1.84)	-0.16 (-5.65, 5.32) 0.953 [-0.02 (-0.64, 0.60)]
Week 4		17 12.8 (11.45)			22 12.7 (8.19)		
Week 4 chg		17 -16.3 (10.67)	-15.98 (2.06)		22 -16.2 (7.98)	-16.12 (1.84)	-0.14 (-5.67, 5.39) 0.961 [-0.01 (-0.65, 0.62)]
Week 6		17 12.1 (13.04)			22 11.2 (7.50)		
Week 6 chg		17 -17.0 (11.99)	-16.68 (2.06)		22 -17.7 (8.62)	-17.60 (1.84)	-0.92 (-6.45, 4.61) 0.741 [-0.09 (-0.72, 0.54)]
Week 8		17 13.5 (13.52)			20 8.3 (4.46)		
Week 8 chg		17 -15.6 (12.31)	-15.22 (2.06)		20 -20.0 (8.76)	-19.82 (1.87)	-4.60 (-10.2, 0.98) 0.105 [-0.44 (-1.09, 0.22)]
Week 10		17 12.8 (13.17)			20 6.6 (4.91)		
Week 10 chg		17 -16.3 (11.90)	-15.89 (2.06)		20 -21.7 (8.14)	-21.53 (1.87)	-5.64 (-11.2, -0.06) 0.047 [-0.56 (-1.22, 0.10)]
Week 12		16 12.0 (13.56)			19 6.4 (5.90)		
Week 12 chg		16 -17.2 (12.63)	-16.28 (2.09)		19 -22.3 (9.42)	-21.79 (1.89)	-5.51 (-11.1, 0.11) 0.055 [-0.50 (-1.18, 0.17)]
Week 14		17 11.9 (14.68)			19 5.2 (3.35)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9803
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.414.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	17	-17.2 (13.06)	-16.79 (2.06)	19	-22.8 (8.40)	-22.34 (1.89)	-5.55 (-11.2, 0.05) 0.052 [-0.51 (-1.18, 0.15)]
Week 16	17	11.2 (14.59)		19	4.4 (2.89)		
Week 16 chg	17	-17.9 (13.49)	-17.48 (2.06)	19	-23.6 (8.55)	-23.16 (1.89)	-5.69 (-11.3, -0.09) 0.047 [-0.51 (-1.18, 0.15)]
Week 18	17	10.9 (14.79)		19	3.7 (2.75)		
Week 18 chg	17	-18.2 (13.76)	-17.73 (2.06)	19	-24.3 (8.99)	-23.86 (1.89)	-6.13 (-11.7, -0.53) 0.033 [-0.53 (-1.20, 0.13)]
Week 20	15	9.8 (15.93)		18	3.9 (2.97)		
Week 20 chg	15	-19.0 (14.47)	-17.46 (2.11)	18	-24.5 (9.30)	-23.71 (1.91)	-6.25 (-11.9, -0.56) 0.032 [-0.52 (-1.22, 0.17)]
Week 22	15	8.1 (8.36)		18	5.5 (4.49)		
Week 22 chg	15	-20.3 (10.22)	-18.07 (2.11)	18	-22.9 (9.81)	-22.15 (1.91)	-4.09 (-9.77, 1.60) 0.156 [-0.41 (-1.10, 0.28)]
Week 24	15	7.5 (7.62)		18	4.4 (6.62)		
Week 24 chg	15	-21.0 (9.67)	-18.70 (2.11)	18	-24.0 (10.75)	-23.25 (1.91)	-4.55 (-10.2, 1.14) 0.115 [-0.44 (-1.14, 0.25)]
Week 26	15	7.7 (7.96)		18	5.1 (6.24)		
Week 26 chg	15	-20.8 (9.16)	-18.50 (2.11)	18	-23.3 (11.28)	-22.53 (1.91)	-4.03 (-9.71, 1.66) 0.162 [-0.39 (-1.08, 0.30)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9803
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.414.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 34.6 (13.98)		116	116 32.7 (12.01)		
Week 2		119 21.6 (14.33)			116 19.6 (13.11)		
Week 2 chg		119 -13.1 (11.43)	-12.76 (0.88)		116 -13.1 (11.44)	-13.61 (0.90)	-0.85 (-3.32, 1.63) 0.502 [-0.07 (-0.33, 0.18)]
Week 4		117 16.1 (12.73)			115 13.2 (10.77)		
Week 4 chg		117 -18.5 (12.12)	-17.84 (0.88)		115 -19.3 (10.97)	-20.01 (0.90)	-2.17 (-4.65, 0.32) 0.087 [-0.19 (-0.45, 0.07)]
Week 6		115 15.1 (12.32)			112 11.2 (10.07)		
Week 6 chg		115 -19.6 (12.73)	-18.84 (0.89)		112 -21.5 (12.41)	-22.19 (0.90)	-3.35 (-5.84, -0.85) 0.009 [-0.27 (-0.53, -0.00)]
Week 8		116 14.1 (12.67)			110 9.8 (9.03)		
Week 8 chg		116 -20.5 (13.99)	-19.95 (0.89)		110 -23.0 (12.66)	-23.75 (0.91)	-3.80 (-6.30, -1.31) 0.003 [-0.28 (-0.55, -0.02)]
Week 10		114 12.5 (11.49)			110 7.8 (7.80)		
Week 10 chg		114 -22.2 (14.09)	-21.37 (0.89)		110 -24.7 (12.04)	-25.62 (0.91)	-4.25 (-6.75, -1.75) <.001 [-0.32 (-0.59, -0.06)]
Week 12		112 12.0 (10.90)			109 7.8 (8.14)		
Week 12 chg		112 -22.9 (14.39)	-21.88 (0.89)		109 -25.1 (12.83)	-25.80 (0.91)	-3.92 (-6.43, -1.42) 0.002 [-0.29 (-0.55, -0.02)]
Week 14		109 11.1 (11.08)			108 7.3 (8.91)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9803
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.414.4.1: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	-23.7 (14.79)	-22.72 (0.90)	108	-25.5 (13.96)	-26.31 (0.91)	-3.58 (-6.10, -1.07) [-0.25 (-0.52, 0.02)]	0.005
Week 16	107	10.4 (10.92)		104	6.8 (8.16)			
Week 16 chg	107	-24.7 (15.00)	-23.49 (0.90)	104	-26.3 (13.40)	-26.66 (0.91)	-3.17 (-5.70, -0.64) [-0.22 (-0.49, 0.05)]	0.014
Week 18	99	10.7 (10.95)		96	6.3 (7.90)			
Week 18 chg	99	-24.5 (14.74)	-23.35 (0.91)	96	-26.8 (12.63)	-26.49 (0.93)	-3.14 (-5.70, -0.57) [-0.23 (-0.51, 0.05)]	0.017
Week 20	92	10.7 (12.03)		99	5.8 (6.99)			
Week 20 chg	92	-24.9 (15.37)	-23.38 (0.93)	99	-27.4 (12.35)	-27.25 (0.92)	-3.86 (-6.44, -1.28) [-0.28 (-0.56, 0.01)]	0.003
Week 22	97	10.9 (11.53)		96	4.9 (6.18)			
Week 22 chg	97	-24.9 (15.15)	-23.12 (0.92)	96	-28.2 (12.43)	-27.99 (0.93)	-4.88 (-7.45, -2.30) [-0.35 (-0.64, -0.07)]	<.001
Week 24	97	10.3 (11.42)		99	5.5 (7.33)			
Week 24 chg	97	-25.5 (14.93)	-23.48 (0.92)	99	-27.6 (12.31)	-27.63 (0.92)	-4.15 (-6.72, -1.58) [-0.30 (-0.59, -0.02)]	0.002
Week 26	103	9.3 (10.44)		107	5.7 (8.17)			
Week 26 chg	103	-26.2 (14.19)	-24.56 (0.91)	107	-27.1 (13.04)	-27.76 (0.91)	-3.21 (-5.74, -0.67) [-0.24 (-0.51, 0.04)]	0.013

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9803
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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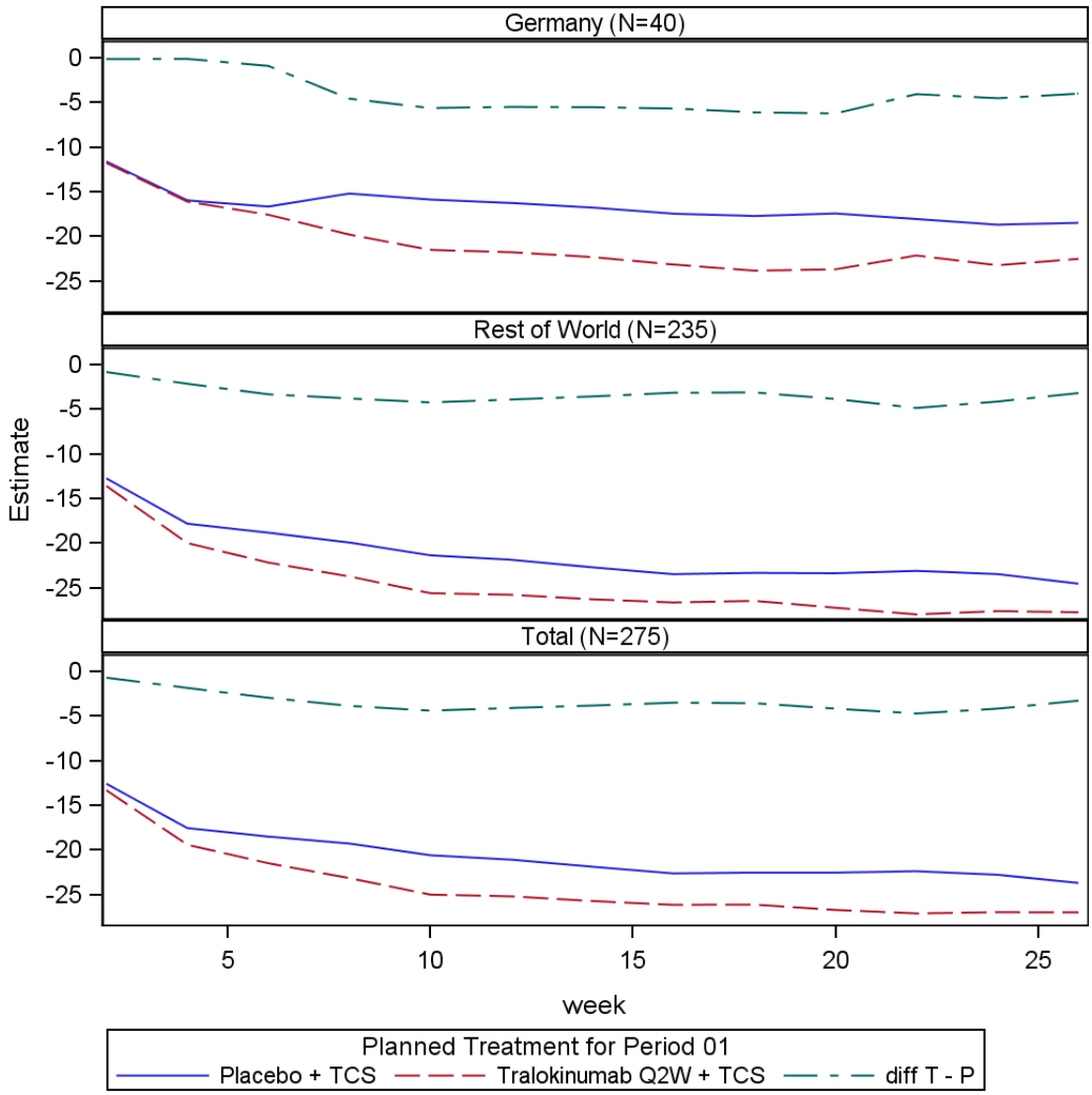
Figure 1.16.414.4.2: Total, Region, change in EASI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)									
Total									
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)		
Week 1		135	6.3 (1.69)			136	6.0 (1.78)		
Week 1 chg		135	-1.1 (1.34)	-1.12 (0.18)		136	-1.2 (1.31)	-1.22 (0.18)	-0.10 (-0.60, 0.40) 0.699 [-0.07 (-0.31, 0.16)]
Week 2		134	5.8 (1.97)			132	5.4 (2.11)		
Week 2 chg		134	-1.7 (1.78)	-1.67 (0.18)		132	-1.9 (1.67)	-1.92 (0.18)	-0.24 (-0.74, 0.26) 0.338 [-0.14 (-0.38, 0.10)]
Week 3		133	5.3 (2.17)			131	4.8 (2.08)		
Week 3 chg		133	-2.2 (2.12)	-2.11 (0.18)		131	-2.5 (1.84)	-2.53 (0.18)	-0.42 (-0.92, 0.08) 0.097 [-0.21 (-0.46, 0.03)]
Week 4		130	5.1 (2.25)			133	4.4 (2.14)		
Week 4 chg		130	-2.4 (2.14)	-2.29 (0.18)		133	-2.8 (1.92)	-2.87 (0.18)	-0.58 (-1.08, -0.08) 0.023 [-0.29 (-0.53, -0.04)]
Week 5		131	4.9 (2.37)			129	4.2 (2.15)		
Week 5 chg		131	-2.6 (2.26)	-2.53 (0.18)		129	-3.1 (1.92)	-3.16 (0.18)	-0.63 (-1.13, -0.13) 0.014 [-0.30 (-0.54, -0.06)]
Week 6		130	4.8 (2.35)			129	4.2 (2.16)		
Week 6 chg		130	-2.7 (2.25)	-2.55 (0.18)		129	-3.1 (1.99)	-3.15 (0.18)	-0.61 (-1.11, -0.10) 0.018 [-0.29 (-0.53, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	4.7 (2.24)		128	4.0 (2.13)			
Week 7 chg	129	-2.8 (2.25)	-2.69 (0.18)	128	-3.3 (2.05)	-3.38 (0.18)	-0.69 (-1.19, -0.19) [-0.32 (-0.57, -0.07)]	0.007
Week 8	127	4.7 (2.32)		125	3.7 (2.10)			
Week 8 chg	127	-2.8 (2.27)	-2.69 (0.18)	125	-3.7 (1.96)	-3.65 (0.18)	-0.96 (-1.46, -0.46) [-0.45 (-0.70, -0.20)]	<.001
Week 9	127	4.6 (2.37)		127	3.6 (2.10)			
Week 9 chg	127	-2.9 (2.32)	-2.76 (0.18)	127	-3.7 (2.03)	-3.71 (0.18)	-0.95 (-1.45, -0.45) [-0.44 (-0.69, -0.19)]	<.001
Week 10	125	4.5 (2.42)		122	3.6 (2.11)			
Week 10 chg	125	-2.9 (2.39)	-2.84 (0.18)	122	-3.7 (1.93)	-3.70 (0.18)	-0.87 (-1.37, -0.36) [-0.40 (-0.65, -0.15)]	<.001
Week 11	128	4.4 (2.41)		126	3.5 (2.15)			
Week 11 chg	128	-3.1 (2.40)	-3.03 (0.18)	126	-3.7 (1.97)	-3.76 (0.18)	-0.73 (-1.23, -0.23) [-0.33 (-0.58, -0.09)]	0.004
Week 12	123	4.4 (2.36)		121	3.5 (2.08)			
Week 12 chg	123	-3.1 (2.41)	-2.99 (0.18)	121	-3.8 (2.06)	-3.82 (0.18)	-0.83 (-1.33, -0.32) [-0.37 (-0.62, -0.12)]	0.001
Week 13	116	4.3 (2.38)		120	3.3 (2.06)			
Week 13 chg	116	-3.3 (2.35)	-3.05 (0.18)	120	-4.0 (2.09)	-3.92 (0.18)	-0.87 (-1.38, -0.37) [-0.39 (-0.65, -0.14)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	123	4.2 (2.38)		123	3.4 (2.13)		
Week 14 chg	123	-3.3 (2.33)	-3.11 (0.18)	123	-3.9 (2.12)	-3.85 (0.18)	-0.74 (-1.25, -0.24) 0.004 [-0.33 (-0.59, -0.08)]
Week 15	123	4.2 (2.31)		123	3.4 (2.11)		
Week 15 chg	123	-3.3 (2.32)	-3.17 (0.18)	123	-4.0 (2.15)	-3.93 (0.18)	-0.76 (-1.26, -0.25) 0.003 [-0.34 (-0.59, -0.09)]
Week 16	121	4.2 (2.29)		122	3.4 (2.05)		
Week 16 chg	121	-3.3 (2.35)	-3.09 (0.18)	122	-3.9 (2.06)	-3.95 (0.18)	-0.85 (-1.36, -0.35) <.001 [-0.39 (-0.64, -0.13)]
Week 17	121	4.3 (2.46)		121	3.4 (2.13)		
Week 17 chg	121	-3.2 (2.49)	-3.09 (0.18)	121	-3.9 (2.04)	-3.93 (0.18)	-0.84 (-1.35, -0.34) 0.001 [-0.37 (-0.63, -0.12)]
Week 18	120	4.4 (2.51)		123	3.3 (2.12)		
Week 18 chg	120	-3.2 (2.46)	-3.04 (0.18)	123	-4.0 (2.11)	-3.96 (0.18)	-0.93 (-1.43, -0.42) <.001 [-0.40 (-0.66, -0.15)]
Week 19	119	4.3 (2.65)		117	3.1 (2.11)		
Week 19 chg	119	-3.3 (2.55)	-3.09 (0.18)	117	-4.2 (2.19)	-4.16 (0.18)	-1.07 (-1.58, -0.57) <.001 [-0.45 (-0.71, -0.19)]
Week 20	120	4.3 (2.68)		118	3.0 (2.02)		
Week 20 chg	120	-3.3 (2.61)	-3.08 (0.18)	118	-4.2 (2.13)	-4.13 (0.18)	-1.05 (-1.56, -0.54) <.001 [-0.44 (-0.70, -0.18)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21	118	4.2 (2.59)		115	3.0 (1.94)		
Week 21 chg	118	-3.4 (2.59)	-3.21 (0.18)	115	-4.3 (2.07)	-4.22 (0.18)	-1.01 (-1.52, -0.50) <.001 [-0.43 (-0.69, -0.17)]
Week 22	120	4.2 (2.64)		116	3.0 (1.90)		
Week 22 chg	120	-3.4 (2.64)	-3.23 (0.18)	116	-4.2 (2.06)	-4.23 (0.18)	-1.01 (-1.51, -0.50) <.001 [-0.42 (-0.68, -0.17)]
Week 23	120	4.1 (2.62)		114	3.0 (1.94)		
Week 23 chg	120	-3.5 (2.58)	-3.28 (0.18)	114	-4.3 (2.15)	-4.23 (0.18)	-0.95 (-1.46, -0.44) <.001 [-0.40 (-0.66, -0.14)]
Week 24	120	4.1 (2.52)		112	2.9 (1.92)		
Week 24 chg	120	-3.4 (2.53)	-3.26 (0.18)	112	-4.3 (2.13)	-4.28 (0.18)	-1.02 (-1.53, -0.51) <.001 [-0.43 (-0.69, -0.17)]
Week 25	114	3.8 (2.46)		115	2.9 (1.90)		
Week 25 chg	114	-3.8 (2.50)	-3.46 (0.18)	115	-4.3 (2.08)	-4.34 (0.18)	-0.88 (-1.39, -0.37) <.001 [-0.38 (-0.65, -0.12)]
Week 26	112	3.9 (2.49)		118	3.0 (1.91)		
Week 26 chg	112	-3.6 (2.56)	-3.32 (0.18)	118	-4.3 (2.11)	-4.28 (0.18)	-0.96 (-1.47, -0.45) <.001 [-0.41 (-0.67, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Germany								
Baseline	18	18 7.9 (1.35)		22	22 7.1 (1.41)			
Week 1		18 6.5 (1.62)			21 5.9 (1.94)			
Week 1 chg		18 -1.4 (1.43)	-1.33 (0.56)		21 -1.2 (1.18)	-1.15 (0.50)	0.18 (-1.36, 1.72) [0.14 (-0.49, 0.77)]	0.816
Week 2		18 5.8 (2.46)			21 5.3 (1.84)			
Week 2 chg		18 -2.1 (2.42)	-2.00 (0.56)		21 -1.8 (1.18)	-1.93 (0.50)	0.07 (-1.47, 1.61) [0.04 (-0.59, 0.67)]	0.929
Week 3		17 5.4 (2.44)			21 4.9 (2.02)			
Week 3 chg		17 -2.5 (2.56)	-2.20 (0.56)		21 -2.2 (1.52)	-2.38 (0.50)	-0.18 (-1.73, 1.36) [-0.09 (-0.73, 0.55)]	0.812
Week 4		17 5.2 (2.86)			21 4.5 (1.89)			
Week 4 chg		17 -2.7 (2.55)	-2.47 (0.56)		21 -2.6 (1.59)	-2.74 (0.50)	-0.27 (-1.81, 1.28) [-0.13 (-0.77, 0.51)]	0.729
Week 5		17 4.7 (2.96)			22 4.2 (1.96)			
Week 5 chg		17 -3.2 (2.77)	-2.92 (0.56)		22 -2.9 (1.76)	-2.98 (0.50)	-0.06 (-1.60, 1.48) [-0.03 (-0.66, 0.61)]	0.940
Week 6		17 4.9 (2.71)			20 4.5 (2.06)			
Week 6 chg		17 -3.0 (2.54)	-2.70 (0.56)		20 -2.6 (1.84)	-2.90 (0.50)	-0.20 (-1.74, 1.35) [-0.09 (-0.74, 0.56)]	0.800
Week 7		17 4.6 (2.70)			20 4.0 (2.26)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg		17	-3.3 (2.61)	-2.93	(0.56)		20	-3.1 (2.06)	-3.33	(0.50)	-0.41 (-1.95, 1.14) [-0.17 (-0.82, 0.47)]	0.601
Week 8		17	4.8 (2.97)				20	3.7 (2.15)				
Week 8 chg		17	-3.2 (3.00)	-2.78	(0.56)		20	-3.5 (1.93)	-3.66	(0.50)	-0.88 (-2.43, 0.67) [-0.36 (-1.01, 0.30)]	0.259
Week 9		16	5.0 (2.85)				20	3.6 (2.06)				
Week 9 chg		16	-2.9 (2.96)	-2.59	(0.57)		20	-3.6 (2.14)	-3.62	(0.50)	-1.03 (-2.57, 0.52) [-0.40 (-1.07, 0.26)]	0.189
Week 10		15	5.4 (2.92)				19	3.4 (2.12)				
Week 10 chg		15	-2.6 (3.12)	-2.47	(0.57)		19	-3.7 (1.95)	-3.85	(0.50)	-1.38 (-2.94, 0.18) [-0.54 (-1.23, 0.14)]	0.082
Week 11		16	5.2 (2.91)				19	3.3 (2.35)				
Week 11 chg		16	-2.7 (3.03)	-2.47	(0.57)		19	-3.8 (2.01)	-3.88	(0.50)	-1.41 (-2.96, 0.14) [-0.56 (-1.24, 0.12)]	0.074
Week 12		14	4.4 (2.74)				18	3.4 (2.07)				
Week 12 chg		14	-3.3 (3.21)	-2.84	(0.57)		18	-3.7 (1.87)	-3.98	(0.51)	-1.14 (-2.71, 0.42) [-0.45 (-1.16, 0.26)]	0.148
Week 13		13	5.0 (2.92)				17	2.6 (1.34)				
Week 13 chg		13	-2.7 (3.43)	-2.44	(0.58)		17	-4.3 (1.50)	-4.45	(0.51)	-2.01 (-3.59, -0.43) [-0.80 (-1.55, -0.05)]	0.013
Week 14		14	4.9 (2.66)				16	2.8 (2.00)				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg		14	-2.9 (3.03)	-2.72	(0.57)		16	-4.4 (1.46)	-4.13	(0.51)	-1.41 (-2.99, 0.16) [-0.61 (-1.34, 0.13)]	0.077
Week 15		16	4.8 (2.68)				17	3.2 (2.06)				
Week 15 chg		16	-3.1 (2.90)	-2.83	(0.57)		17	-3.8 (1.97)	-3.84	(0.51)	-1.01 (-2.58, 0.55) [-0.41 (-1.10, 0.28)]	0.200
Week 16		14	4.6 (2.77)				17	3.3 (2.14)				
Week 16 chg		14	-3.4 (3.21)	-2.79	(0.57)		17	-3.7 (1.96)	-3.77	(0.51)	-0.98 (-2.56, 0.60) [-0.38 (-1.09, 0.34)]	0.218
Week 17		15	4.7 (2.94)				17	3.1 (1.85)				
Week 17 chg		15	-3.2 (3.31)	-2.84	(0.57)		17	-3.9 (1.72)	-3.92	(0.51)	-1.09 (-2.66, 0.48) [-0.42 (-1.12, 0.28)]	0.171
Week 18		15	4.6 (2.69)				17	3.0 (2.18)				
Week 18 chg		15	-3.3 (2.96)	-3.05	(0.57)		17	-3.9 (1.96)	-3.94	(0.51)	-0.89 (-2.46, 0.68) [-0.36 (-1.06, 0.34)]	0.258
Week 19		15	4.4 (2.80)				16	2.6 (1.77)				
Week 19 chg		15	-3.5 (2.74)	-3.31	(0.57)		16	-4.3 (1.89)	-4.07	(0.52)	-0.76 (-2.33, 0.82) [-0.32 (-1.03, 0.39)]	0.341
Week 20		16	4.5 (2.71)				17	2.8 (1.89)				
Week 20 chg		16	-3.4 (2.60)	-3.29	(0.57)		17	-4.2 (1.91)	-3.78	(0.51)	-0.49 (-2.05, 1.08) [-0.21 (-0.90, 0.47)]	0.536
Week 21		15	4.2 (2.38)				15	2.6 (1.47)				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	15	-3.6 (2.57)	-3.30 (0.57)	15	-4.2 (1.62)	-4.11 (0.52)	-0.81 (-2.39, 0.77) 0.309 [-0.38 (-1.10, 0.34)]
Week 22	15	4.3 (2.62)		17	2.6 (1.82)		
Week 22 chg	15	-3.5 (2.95)	-3.13 (0.57)	17	-4.3 (2.04)	-4.10 (0.51)	-0.97 (-2.54, 0.60) 0.221 [-0.39 (-1.09, 0.31)]
Week 23	15	4.3 (2.68)		16	2.5 (1.43)		
Week 23 chg	15	-3.5 (3.12)	-3.07 (0.57)	16	-4.4 (1.73)	-4.36 (0.52)	-1.29 (-2.87, 0.29) 0.106 [-0.52 (-1.23, 0.20)]
Week 24	15	4.5 (2.94)		16	2.6 (1.71)		
Week 24 chg	15	-3.4 (3.33)	-2.99 (0.57)	16	-4.3 (1.68)	-4.35 (0.52)	-1.35 (-2.93, 0.22) 0.090 [-0.52 (-1.24, 0.20)]
Week 25	14	3.9 (2.76)		17	2.8 (1.64)		
Week 25 chg	14	-3.8 (3.26)	-3.35 (0.57)	17	-4.2 (1.62)	-4.09 (0.51)	-0.74 (-2.31, 0.83) 0.348 [-0.30 (-1.01, 0.41)]
Week 26	14	4.1 (2.83)		17	3.0 (1.86)		
Week 26 chg	14	-3.7 (3.28)	-3.24 (0.57)	17	-4.0 (1.69)	-3.89 (0.51)	-0.65 (-2.22, 0.92) 0.413 [-0.26 (-0.97, 0.45)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	118 7.4 (1.37)		116	115 7.3 (1.47)		
Week 1		117 6.3 (1.71)			115 6.1 (1.76)		
Week 1 chg		117 -1.1 (1.33)	-1.10 (0.19)		115 -1.2 (1.34)	-1.23 (0.19)	-0.13 (-0.67, 0.40) 0.621 [-0.10 (-0.36, 0.16)]
Week 2		116 5.8 (1.90)			111 5.4 (2.16)		
Week 2 chg		116 -1.6 (1.66)	-1.62 (0.19)		111 -1.9 (1.75)	-1.92 (0.19)	-0.30 (-0.83, 0.24) 0.274 [-0.18 (-0.44, 0.09)]
Week 3		116 5.3 (2.13)			110 4.7 (2.10)		
Week 3 chg		116 -2.1 (2.05)	-2.09 (0.19)		110 -2.6 (1.89)	-2.57 (0.19)	-0.47 (-1.01, 0.06) 0.082 [-0.24 (-0.50, 0.02)]
Week 4		113 5.1 (2.16)			112 4.4 (2.19)		
Week 4 chg		113 -2.3 (2.08)	-2.26 (0.19)		112 -2.9 (1.98)	-2.89 (0.19)	-0.63 (-1.17, -0.09) 0.021 [-0.31 (-0.57, -0.05)]
Week 5		114 4.9 (2.28)			107 4.2 (2.20)		
Week 5 chg		114 -2.6 (2.18)	-2.47 (0.19)		107 -3.2 (1.96)	-3.19 (0.19)	-0.73 (-1.26, -0.19) 0.008 [-0.35 (-0.62, -0.08)]
Week 6		113 4.8 (2.30)			109 4.2 (2.18)		
Week 6 chg		113 -2.6 (2.21)	-2.52 (0.19)		109 -3.2 (2.01)	-3.20 (0.19)	-0.68 (-1.22, -0.15) 0.013 [-0.32 (-0.59, -0.06)]
Week 7		112 4.7 (2.18)			108 4.0 (2.12)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	112	-2.8 (2.19)	-2.66 (0.19)	108	-3.4 (2.06)	-3.39 (0.19)	-0.73 (-1.27, -0.19) [-0.34 (-0.61, -0.08)]	0.008
Week 8	110	4.7 (2.22)		105	3.7 (2.10)			
Week 8 chg	110	-2.8 (2.14)	-2.67 (0.19)	105	-3.7 (1.97)	-3.66 (0.20)	-0.99 (-1.53, -0.45) [-0.48 (-0.75, -0.21)]	<.001
Week 9	111	4.6 (2.31)		107	3.6 (2.12)			
Week 9 chg	111	-2.9 (2.23)	-2.77 (0.19)	107	-3.7 (2.01)	-3.74 (0.19)	-0.97 (-1.51, -0.43) [-0.46 (-0.73, -0.19)]	<.001
Week 10	110	4.4 (2.33)		103	3.7 (2.11)			
Week 10 chg	110	-3.0 (2.28)	-2.87 (0.19)	103	-3.7 (1.94)	-3.69 (0.20)	-0.82 (-1.36, -0.28) [-0.39 (-0.66, -0.11)]	0.003
Week 11	112	4.3 (2.32)		107	3.6 (2.13)			
Week 11 chg	112	-3.2 (2.30)	-3.10 (0.19)	107	-3.7 (1.98)	-3.74 (0.20)	-0.64 (-1.18, -0.11) [-0.30 (-0.57, -0.03)]	0.019
Week 12	109	4.3 (2.33)		103	3.5 (2.09)			
Week 12 chg	109	-3.1 (2.31)	-3.00 (0.19)	103	-3.8 (2.10)	-3.80 (0.20)	-0.80 (-1.34, -0.26) [-0.36 (-0.63, -0.09)]	0.004
Week 13	103	4.2 (2.30)		103	3.4 (2.15)			
Week 13 chg	103	-3.3 (2.19)	-3.11 (0.19)	103	-3.9 (2.17)	-3.85 (0.20)	-0.74 (-1.28, -0.20) [-0.34 (-0.61, -0.06)]	0.008
Week 14	109	4.2 (2.35)		107	3.5 (2.14)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	109	-3.3 (2.24)	-3.16	(0.19)	107	107	-3.8 (2.20)	-3.82	(0.20)	-0.66 (-1.20, -0.12) [-0.30 (-0.57, -0.03)]	0.016
Week 15	107	107	4.2 (2.25)			106	106	3.4 (2.12)				
Week 15 chg	107	107	-3.4 (2.24)	-3.22	(0.19)	106	106	-4.0 (2.18)	-3.95	(0.20)	-0.73 (-1.28, -0.19) [-0.33 (-0.60, -0.06)]	0.008
Week 16	107	107	4.2 (2.23)			105	105	3.4 (2.05)				
Week 16 chg	107	107	-3.3 (2.23)	-3.12	(0.19)	105	105	-3.9 (2.09)	-3.98	(0.20)	-0.86 (-1.40, -0.32) [-0.40 (-0.67, -0.13)]	0.002
Week 17	106	106	4.3 (2.40)			104	104	3.4 (2.17)				
Week 17 chg	106	106	-3.3 (2.37)	-3.11	(0.19)	104	104	-3.9 (2.10)	-3.95	(0.20)	-0.84 (-1.38, -0.30) [-0.37 (-0.65, -0.10)]	0.003
Week 18	105	105	4.4 (2.50)			106	106	3.3 (2.12)				
Week 18 chg	105	105	-3.1 (2.40)	-3.03	(0.19)	106	106	-4.0 (2.14)	-3.97	(0.20)	-0.94 (-1.48, -0.40) [-0.42 (-0.69, -0.14)]	<.001
Week 19	104	104	4.3 (2.64)			101	101	3.1 (2.16)				
Week 19 chg	104	104	-3.2 (2.53)	-3.05	(0.19)	101	101	-4.2 (2.24)	-4.17	(0.20)	-1.11 (-1.66, -0.57) [-0.47 (-0.74, -0.19)]	<.001
Week 20	104	104	4.3 (2.69)			101	101	3.1 (2.05)				
Week 20 chg	104	104	-3.2 (2.63)	-3.05	(0.19)	101	101	-4.2 (2.17)	-4.17	(0.20)	-1.12 (-1.66, -0.58) [-0.46 (-0.74, -0.19)]	<.001
Week 21	103	103	4.1 (2.64)			100	100	3.0 (2.00)				

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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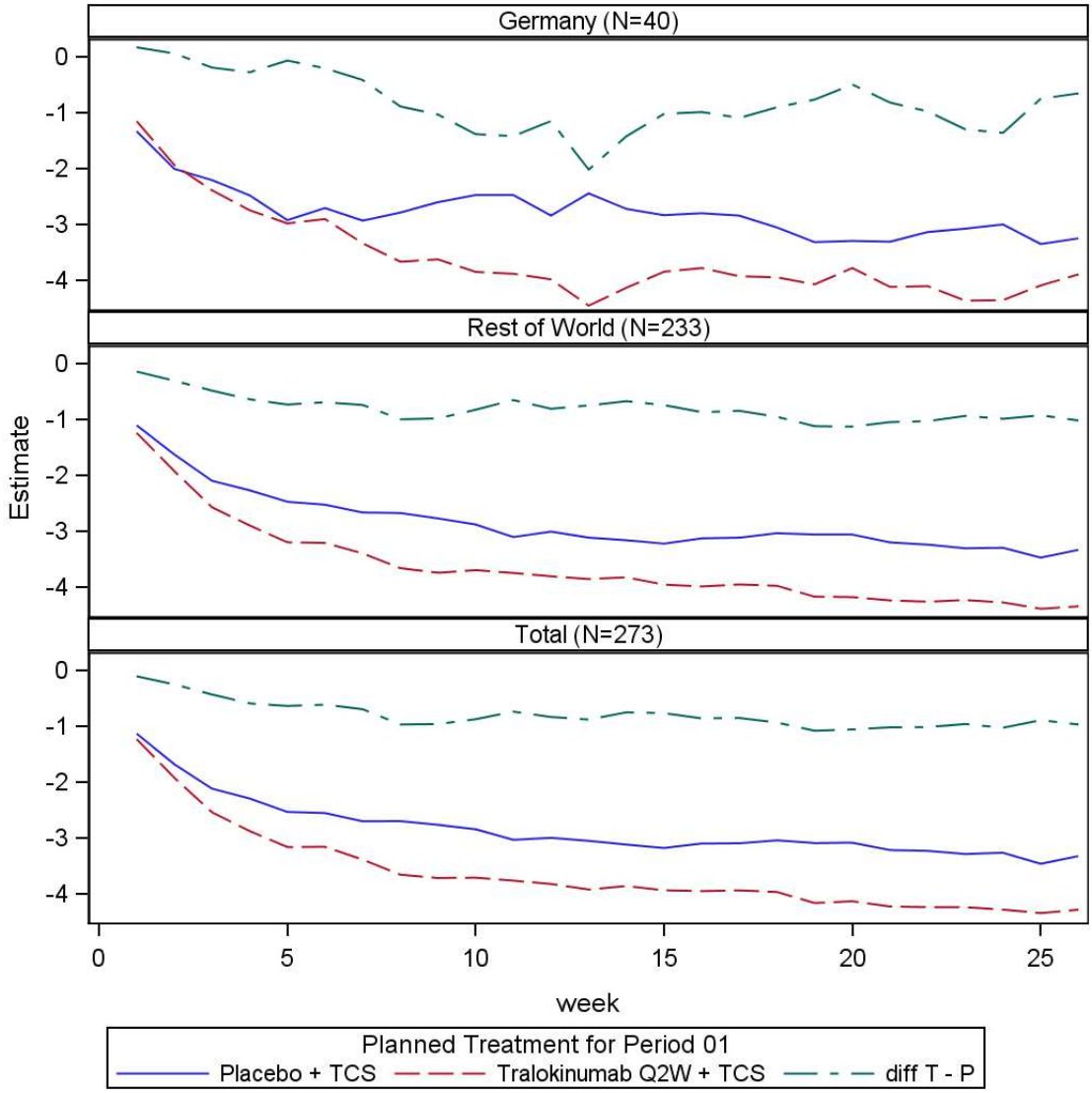
Table 1.16.416.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	103	-3.4 (2.60)	-3.20 (0.19)	100	-4.3 (2.14)	-4.23 (0.20)	-1.04 (-1.58, -0.50) <.001 [-0.44 (-0.71, -0.16)]
Week 22	105	4.1 (2.65)		99	3.0 (1.92)		
Week 22 chg	105	-3.4 (2.61)	-3.23 (0.19)	99	-4.2 (2.08)	-4.26 (0.20)	-1.02 (-1.57, -0.48) <.001 [-0.43 (-0.71, -0.15)]
Week 23	105	4.1 (2.62)		98	3.0 (2.00)		
Week 23 chg	105	-3.5 (2.51)	-3.30 (0.19)	98	-4.2 (2.21)	-4.23 (0.20)	-0.93 (-1.47, -0.38) <.001 [-0.39 (-0.67, -0.11)]
Week 24	105	4.1 (2.47)		96	3.0 (1.96)		
Week 24 chg	105	-3.5 (2.42)	-3.29 (0.19)	96	-4.3 (2.20)	-4.27 (0.20)	-0.98 (-1.52, -0.43) <.001 [-0.42 (-0.70, -0.14)]
Week 25	100	3.8 (2.44)		98	2.9 (1.95)		
Week 25 chg	100	-3.7 (2.39)	-3.47 (0.19)	98	-4.4 (2.16)	-4.38 (0.20)	-0.92 (-1.46, -0.37) 0.001 [-0.40 (-0.68, -0.12)]
Week 26	98	3.9 (2.46)		101	3.0 (1.93)		
Week 26 chg	98	-3.6 (2.46)	-3.33 (0.20)	101	-4.3 (2.18)	-4.34 (0.20)	-1.01 (-1.56, -0.47) <.001 [-0.44 (-0.72, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8553
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.416.4.2: Total, Region, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 1		135 5.8 (2.01)			136 5.2 (2.21)		
Week 1 chg		135 -1.1 (1.50)	-1.05 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.10 (-0.61, 0.42) 0.715 [-0.07 (-0.30, 0.17)]
Week 2		134 5.2 (2.29)			132 4.5 (2.45)		
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.19)	-0.18 (-0.70, 0.34) 0.502 [-0.09 (-0.33, 0.15)]
Week 3		133 4.7 (2.36)			131 3.9 (2.35)		
Week 3 chg		133 -2.2 (2.17)	-2.12 (0.19)		131 -2.4 (2.01)	-2.49 (0.19)	-0.37 (-0.89, 0.15) 0.165 [-0.18 (-0.42, 0.07)]
Week 4		130 4.5 (2.48)			133 3.6 (2.39)		
Week 4 chg		130 -2.4 (2.23)	-2.25 (0.19)		133 -2.7 (2.06)	-2.79 (0.19)	-0.54 (-1.06, -0.02) 0.041 [-0.25 (-0.50, -0.01)]
Week 5		131 4.2 (2.55)			129 3.3 (2.42)		
Week 5 chg		131 -2.7 (2.37)	-2.54 (0.19)		129 -3.0 (2.16)	-3.13 (0.19)	-0.59 (-1.11, -0.07) 0.027 [-0.26 (-0.50, -0.01)]
Week 6		130 4.2 (2.52)			129 3.3 (2.42)		
Week 6 chg		130 -2.7 (2.36)	-2.50 (0.19)		129 -3.1 (2.24)	-3.21 (0.19)	-0.71 (-1.23, -0.19) 0.008 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	3.9 (2.43)		128	3.1 (2.37)			
Week 7 chg	129	-3.0 (2.38)	-2.77 (0.19)	128	-3.3 (2.28)	-3.41 (0.19)	-0.64 (-1.16, -0.12) [-0.27 (-0.52, -0.03)]	0.016
Week 8	127	3.9 (2.46)		125	2.8 (2.29)			
Week 8 chg	127	-3.0 (2.32)	-2.75 (0.19)	125	-3.6 (2.26)	-3.65 (0.19)	-0.90 (-1.42, -0.38) [-0.39 (-0.64, -0.14)]	<.001
Week 9	127	3.8 (2.49)		127	2.6 (2.22)			
Week 9 chg	127	-3.1 (2.33)	-2.89 (0.19)	127	-3.7 (2.23)	-3.84 (0.19)	-0.95 (-1.47, -0.43) [-0.41 (-0.66, -0.17)]	<.001
Week 10	125	3.7 (2.54)		122	2.7 (2.29)			
Week 10 chg	125	-3.2 (2.40)	-3.00 (0.19)	122	-3.7 (2.29)	-3.82 (0.19)	-0.82 (-1.34, -0.30) [-0.35 (-0.60, -0.10)]	0.002
Week 11	128	3.6 (2.46)		126	2.6 (2.22)			
Week 11 chg	128	-3.3 (2.40)	-3.11 (0.19)	126	-3.8 (2.26)	-3.90 (0.19)	-0.78 (-1.31, -0.26) [-0.34 (-0.58, -0.09)]	0.003
Week 12	123	3.5 (2.44)		121	2.5 (2.21)			
Week 12 chg	123	-3.4 (2.45)	-3.14 (0.19)	121	-3.8 (2.38)	-4.00 (0.19)	-0.86 (-1.38, -0.33) [-0.36 (-0.61, -0.10)]	0.001
Week 13	116	3.4 (2.40)		120	2.3 (2.13)			
Week 13 chg	116	-3.6 (2.32)	-3.27 (0.19)	120	-3.9 (2.26)	-4.04 (0.19)	-0.77 (-1.30, -0.25) [-0.34 (-0.59, -0.08)]	0.004

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	123	3.3 (2.42)		123	2.4 (2.18)		
Week 14 chg	123	-3.5 (2.33)	-3.34 (0.19)	123	-3.9 (2.27)	-4.04 (0.19)	-0.70 (-1.22, -0.18) 0.009 [-0.30 (-0.56, -0.05)]
Week 15	123	3.3 (2.47)		123	2.4 (2.18)		
Week 15 chg	123	-3.7 (2.35)	-3.43 (0.19)	123	-3.9 (2.35)	-4.08 (0.19)	-0.65 (-1.17, -0.12) 0.015 [-0.28 (-0.53, -0.02)]
Week 16	121	3.2 (2.40)		122	2.5 (2.17)		
Week 16 chg	121	-3.7 (2.28)	-3.40 (0.19)	122	-3.9 (2.32)	-4.07 (0.19)	-0.67 (-1.20, -0.15) 0.012 [-0.29 (-0.55, -0.04)]
Week 17	121	3.4 (2.55)		121	2.4 (2.30)		
Week 17 chg	121	-3.6 (2.46)	-3.34 (0.19)	121	-4.0 (2.36)	-4.10 (0.19)	-0.76 (-1.28, -0.23) 0.005 [-0.31 (-0.57, -0.06)]
Week 18	120	3.4 (2.65)		123	2.3 (2.24)		
Week 18 chg	120	-3.6 (2.51)	-3.35 (0.19)	123	-4.0 (2.40)	-4.15 (0.19)	-0.79 (-1.31, -0.27) 0.003 [-0.32 (-0.58, -0.07)]
Week 19	119	3.3 (2.75)		117	2.2 (2.22)		
Week 19 chg	119	-3.7 (2.57)	-3.42 (0.19)	117	-4.1 (2.46)	-4.23 (0.19)	-0.81 (-1.33, -0.28) 0.003 [-0.32 (-0.58, -0.06)]
Week 20	120	3.4 (2.78)		118	2.2 (2.12)		
Week 20 chg	120	-3.6 (2.63)	-3.32 (0.19)	118	-4.1 (2.42)	-4.18 (0.19)	-0.87 (-1.39, -0.34) 0.001 [-0.34 (-0.60, -0.09)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21	118	3.2 (2.67)		115	2.1 (2.04)		
Week 21 chg	118	-3.8 (2.62)	-3.49 (0.19)	115	-4.2 (2.37)	-4.32 (0.19)	-0.83 (-1.36, -0.30) 0.002 [-0.33 (-0.59, -0.07)]
Week 22	120	3.3 (2.72)		116	2.0 (1.98)		
Week 22 chg	120	-3.7 (2.65)	-3.37 (0.19)	116	-4.3 (2.35)	-4.38 (0.19)	-1.00 (-1.53, -0.48) <.001 [-0.40 (-0.66, -0.14)]
Week 23	120	3.2 (2.64)		114	2.0 (2.02)		
Week 23 chg	120	-3.7 (2.56)	-3.45 (0.19)	114	-4.2 (2.44)	-4.35 (0.19)	-0.90 (-1.43, -0.37) <.001 [-0.36 (-0.62, -0.10)]
Week 24	120	3.2 (2.59)		112	2.0 (1.91)		
Week 24 chg	120	-3.8 (2.57)	-3.52 (0.19)	112	-4.2 (2.37)	-4.38 (0.19)	-0.86 (-1.39, -0.34) 0.001 [-0.35 (-0.61, -0.09)]
Week 25	114	2.8 (2.49)		115	2.0 (1.97)		
Week 25 chg	114	-4.1 (2.53)	-3.71 (0.19)	115	-4.3 (2.44)	-4.41 (0.19)	-0.70 (-1.23, -0.17) 0.010 [-0.28 (-0.54, -0.02)]
Week 26	112	2.9 (2.50)		118	2.1 (1.98)		
Week 26 chg	112	-4.0 (2.55)	-3.62 (0.19)	118	-4.2 (2.48)	-4.34 (0.19)	-0.72 (-1.25, -0.19) 0.008 [-0.29 (-0.55, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 7.3 (1.71)		22	22 6.1 (1.80)		
Week 1		18 6.0 (2.07)			21 4.8 (2.29)		
Week 1 chg		18 -1.4 (1.63)	-1.27 (0.56)		21 -1.4 (1.42)	-1.36 (0.51)	-0.09 (-1.66, 1.47) 0.907 [-0.06 (-0.69, 0.57)]
Week 2		18 5.1 (2.65)			21 4.4 (2.15)		
Week 2 chg		18 -2.2 (2.38)	-2.08 (0.56)		21 -1.7 (1.30)	-1.89 (0.51)	0.18 (-1.38, 1.75) 0.813 [0.10 (-0.53, 0.73)]
Week 3		17 4.6 (2.73)			21 3.7 (2.26)		
Week 3 chg		17 -2.7 (2.76)	-2.36 (0.56)		21 -2.3 (1.56)	-2.64 (0.51)	-0.28 (-1.85, 1.30) 0.725 [-0.13 (-0.77, 0.51)]
Week 4		17 4.6 (3.17)			21 3.4 (2.18)		
Week 4 chg		17 -2.8 (2.65)	-2.46 (0.56)		21 -2.7 (1.84)	-2.93 (0.51)	-0.48 (-2.05, 1.10) 0.545 [-0.21 (-0.85, 0.43)]
Week 5		17 4.1 (3.11)			22 2.8 (2.21)		
Week 5 chg		17 -3.2 (2.84)	-2.87 (0.56)		22 -3.3 (1.99)	-3.45 (0.50)	-0.59 (-2.15, 0.98) 0.456 [-0.24 (-0.88, 0.39)]
Week 6		17 4.1 (3.09)			20 3.1 (2.42)		
Week 6 chg		17 -3.2 (2.76)	-2.88 (0.56)		20 -2.8 (1.98)	-3.21 (0.51)	-0.33 (-1.91, 1.24) 0.672 [-0.14 (-0.79, 0.51)]
Week 7		17 3.7 (2.98)			20 2.8 (2.37)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	17	-3.6 (2.80)	-3.25 (0.57)	20	-3.4 (2.10)	-3.75 (0.51)	-0.51 (-2.08, 1.06) 0.520 [-0.21 (-0.86, 0.44)]
Week 8	17	3.9 (3.13)		20	2.4 (2.40)		
Week 8 chg	17	-3.4 (2.84)	-3.07 (0.57)	20	-3.8 (2.24)	-4.06 (0.51)	-0.99 (-2.56, 0.58) 0.211 [-0.39 (-1.04, 0.26)]
Week 9	16	4.2 (3.04)		20	2.3 (1.84)		
Week 9 chg	16	-3.1 (2.76)	-2.87 (0.57)	20	-4.0 (2.05)	-4.06 (0.51)	-1.19 (-2.76, 0.38) 0.135 [-0.50 (-1.17, 0.17)]
Week 10	15	4.6 (3.13)		19	2.0 (2.02)		
Week 10 chg	15	-2.8 (2.85)	-2.76 (0.57)	19	-4.2 (2.10)	-4.45 (0.51)	-1.70 (-3.28, -0.11) 0.036 [-0.69 (-1.39, 0.01)]
Week 11	16	4.3 (3.03)		19	2.0 (2.02)		
Week 11 chg	16	-3.1 (2.77)	-2.82 (0.57)	19	-4.2 (2.11)	-4.45 (0.51)	-1.63 (-3.21, -0.05) 0.043 [-0.67 (-1.35, 0.01)]
Week 12	14	3.5 (2.77)		18	2.1 (1.85)		
Week 12 chg	14	-3.6 (2.95)	-3.14 (0.57)	18	-4.0 (2.12)	-4.42 (0.51)	-1.29 (-2.88, 0.30) 0.110 [-0.51 (-1.22, 0.20)]
Week 13	13	3.9 (2.78)		17	1.6 (1.36)		
Week 13 chg	13	-3.3 (2.89)	-2.95 (0.58)	17	-4.5 (1.95)	-4.79 (0.52)	-1.84 (-3.44, -0.24) 0.025 [-0.77 (-1.52, -0.02)]
Week 14	14	4.1 (2.69)		16	1.6 (1.59)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg		14	-3.2 (2.82)	-2.92 (0.57)			16	-4.7 (1.83)	-4.72 (0.52)		-1.80 (-3.40, -0.20) 0.028 [-0.77 (-1.51, -0.02)]
Week 15		16	3.8 (3.22)				17	1.9 (1.60)			
Week 15 chg		16	-3.6 (3.04)	-3.16 (0.57)			17	-4.2 (2.22)	-4.54 (0.52)		-1.38 (-2.97, 0.21) 0.087 [-0.52 (-1.22, 0.17)]
Week 16		14	3.4 (2.94)				17	1.9 (1.85)			
Week 16 chg		14	-4.0 (2.91)	-3.28 (0.58)			17	-4.2 (2.18)	-4.53 (0.52)		-1.25 (-2.85, 0.35) 0.122 [-0.49 (-1.21, 0.22)]
Week 17		15	3.7 (2.96)				17	1.6 (1.24)			
Week 17 chg		15	-3.7 (3.04)	-3.15 (0.57)			17	-4.5 (1.88)	-4.85 (0.52)		-1.70 (-3.29, -0.10) 0.037 [-0.68 (-1.40, 0.03)]
Week 18		15	3.6 (2.93)				17	1.6 (1.29)			
Week 18 chg		15	-3.8 (2.95)	-3.26 (0.57)			17	-4.5 (1.85)	-4.81 (0.52)		-1.54 (-3.14, 0.05) 0.057 [-0.64 (-1.35, 0.07)]
Week 19		15	3.5 (3.05)				16	1.5 (1.43)			
Week 19 chg		15	-3.9 (2.84)	-3.45 (0.57)			16	-4.5 (2.15)	-4.69 (0.52)		-1.24 (-2.84, 0.37) 0.128 [-0.49 (-1.21, 0.22)]
Week 20		16	3.7 (3.03)				17	1.4 (1.50)			
Week 20 chg		16	-3.7 (2.79)	-3.34 (0.57)			17	-4.6 (2.28)	-4.61 (0.52)		-1.27 (-2.86, 0.32) 0.115 [-0.50 (-1.19, 0.19)]
Week 21		15	3.3 (2.74)				15	1.6 (1.41)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	15	-4.0 (2.78)	-3.49 (0.57)	15	-4.3 (2.01)	-4.65 (0.53)	-1.15 (-2.76, 0.46) 0.158 [-0.47 (-1.20, 0.25)]
Week 22	15	3.4 (2.81)		17	1.4 (1.26)		
Week 22 chg	15	-3.9 (2.90)	-3.34 (0.57)	17	-4.6 (2.13)	-4.70 (0.52)	-1.36 (-2.95, 0.24) 0.093 [-0.54 (-1.25, 0.17)]
Week 23	15	3.3 (2.73)		16	1.3 (1.20)		
Week 23 chg	15	-4.0 (3.02)	-3.40 (0.57)	16	-4.7 (2.02)	-4.99 (0.52)	-1.60 (-3.20, 0.00) 0.050 [-0.63 (-1.35, 0.09)]
Week 24	15	3.4 (2.89)		16	1.5 (1.40)		
Week 24 chg	15	-3.8 (3.15)	-3.26 (0.57)	16	-4.4 (1.98)	-4.84 (0.52)	-1.58 (-3.18, 0.03) 0.054 [-0.60 (-1.32, 0.12)]
Week 25	14	3.2 (2.88)		17	1.6 (1.38)		
Week 25 chg	14	-4.0 (3.18)	-3.45 (0.57)	17	-4.4 (2.14)	-4.64 (0.52)	-1.19 (-2.79, 0.41) 0.142 [-0.45 (-1.16, 0.27)]
Week 26	14	3.2 (2.87)		17	1.9 (1.82)		
Week 26 chg	14	-3.9 (3.11)	-3.41 (0.57)	17	-4.0 (2.42)	-4.26 (0.52)	-0.85 (-2.45, 0.74) 0.289 [-0.31 (-1.02, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	119	118 6.8 (1.63)		116	115 6.3 (2.17)			
Week 1		117 5.8 (2.01)			115 5.3 (2.19)			
Week 1 chg		117 -1.1 (1.48)	-1.02 (0.20)		115 -1.1 (1.46)	-1.10 (0.20)	-0.08 (-0.64, 0.47) [-0.06 (-0.31, 0.20)]	0.771
Week 2		116 5.2 (2.24)			111 4.6 (2.52)			
Week 2 chg		116 -1.7 (1.92)	-1.61 (0.20)		111 -1.8 (1.89)	-1.84 (0.20)	-0.23 (-0.78, 0.33) [-0.12 (-0.38, 0.14)]	0.419
Week 3		116 4.7 (2.31)			110 3.9 (2.37)			
Week 3 chg		116 -2.2 (2.08)	-2.09 (0.20)		110 -2.4 (2.09)	-2.46 (0.20)	-0.38 (-0.93, 0.18) [-0.18 (-0.44, 0.08)]	0.184
Week 4		113 4.5 (2.38)			112 3.7 (2.43)			
Week 4 chg		113 -2.3 (2.16)	-2.22 (0.20)		112 -2.7 (2.11)	-2.76 (0.20)	-0.54 (-1.09, 0.02) [-0.25 (-0.51, 0.01)]	0.059
Week 5		114 4.2 (2.47)			107 3.4 (2.46)			
Week 5 chg		114 -2.6 (2.29)	-2.49 (0.20)		107 -3.0 (2.20)	-3.07 (0.20)	-0.57 (-1.13, -0.02) [-0.25 (-0.52, 0.01)]	0.044
Week 6		113 4.2 (2.44)			109 3.3 (2.43)			
Week 6 chg		113 -2.6 (2.29)	-2.45 (0.20)		109 -3.1 (2.29)	-3.19 (0.20)	-0.74 (-1.30, -0.19) [-0.32 (-0.59, -0.06)]	0.009
Week 7		112 3.9 (2.35)			108 3.1 (2.37)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	112	-2.9 (2.31)	-2.70 (0.20)	108	-3.3 (2.32)	-3.34 (0.20)	-0.64 (-1.19, -0.08) 0.026 [-0.27 (-0.54, -0.01)]
Week 8	110	3.9 (2.36)		105	2.9 (2.27)		
Week 8 chg	110	-2.9 (2.23)	-2.71 (0.20)	105	-3.5 (2.28)	-3.57 (0.20)	-0.86 (-1.42, -0.30) 0.003 [-0.38 (-0.65, -0.11)]
Week 9	111	3.8 (2.41)		107	2.7 (2.28)		
Week 9 chg	111	-3.1 (2.28)	-2.89 (0.20)	107	-3.7 (2.27)	-3.80 (0.20)	-0.91 (-1.47, -0.35) 0.002 [-0.40 (-0.67, -0.13)]
Week 10	110	3.6 (2.44)		103	2.8 (2.33)		
Week 10 chg	110	-3.3 (2.34)	-3.02 (0.20)	103	-3.6 (2.32)	-3.70 (0.20)	-0.67 (-1.23, -0.11) 0.018 [-0.29 (-0.56, -0.02)]
Week 11	112	3.5 (2.37)		107	2.7 (2.24)		
Week 11 chg	112	-3.3 (2.35)	-3.15 (0.20)	107	-3.7 (2.29)	-3.80 (0.20)	-0.64 (-1.20, -0.09) 0.024 [-0.28 (-0.54, -0.01)]
Week 12	109	3.5 (2.41)		103	2.6 (2.27)		
Week 12 chg	109	-3.3 (2.40)	-3.14 (0.20)	103	-3.8 (2.43)	-3.93 (0.20)	-0.79 (-1.35, -0.23) 0.006 [-0.33 (-0.60, -0.06)]
Week 13	103	3.3 (2.36)		103	2.4 (2.21)		
Week 13 chg	103	-3.6 (2.26)	-3.30 (0.20)	103	-3.9 (2.31)	-3.92 (0.20)	-0.62 (-1.18, -0.06) 0.031 [-0.27 (-0.55, 0.00)]
Week 14	109	3.3 (2.38)		107	2.5 (2.24)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg		109	-3.6 (2.27)	-3.38	(0.20)		107	-3.8 (2.31)	-3.93	(0.20)	-0.55 (-1.11, 0.01) 0.054 [-0.24 (-0.51, 0.03)]
Week 15		107	3.2 (2.35)				106	2.5 (2.25)			
Week 15 chg		107	-3.7 (2.25)	-3.46	(0.20)		106	-3.9 (2.37)	-4.01	(0.20)	-0.54 (-1.10, 0.02) 0.058 [-0.23 (-0.50, 0.03)]
Week 16		107	3.2 (2.33)				105	2.5 (2.21)			
Week 16 chg		107	-3.7 (2.19)	-3.40	(0.20)		105	-3.8 (2.35)	-3.99	(0.20)	-0.59 (-1.15, -0.03) 0.038 [-0.26 (-0.53, 0.01)]
Week 17		106	3.3 (2.50)				104	2.5 (2.41)			
Week 17 chg		106	-3.6 (2.39)	-3.35	(0.20)		104	-3.9 (2.42)	-3.98	(0.20)	-0.63 (-1.19, -0.07) 0.028 [-0.26 (-0.53, 0.01)]
Week 18		105	3.4 (2.62)				106	2.4 (2.34)			
Week 18 chg		105	-3.6 (2.45)	-3.36	(0.20)		106	-3.9 (2.48)	-4.04	(0.20)	-0.68 (-1.25, -0.12) 0.017 [-0.28 (-0.55, -0.01)]
Week 19		104	3.3 (2.71)				101	2.3 (2.31)			
Week 19 chg		104	-3.7 (2.55)	-3.41	(0.20)		101	-4.0 (2.51)	-4.15	(0.20)	-0.74 (-1.30, -0.17) 0.011 [-0.29 (-0.57, -0.02)]
Week 20		104	3.4 (2.75)				101	2.3 (2.19)			
Week 20 chg		104	-3.6 (2.62)	-3.31	(0.20)		101	-4.0 (2.44)	-4.10	(0.20)	-0.80 (-1.36, -0.23) 0.006 [-0.31 (-0.59, -0.04)]
Week 21		103	3.2 (2.67)				100	2.2 (2.11)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.418.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 21 chg	103	103	-3.7 (2.61)	-3.49	(0.20)	100	100	-4.2 (2.43)	-4.26	(0.20)	-0.78 (-1.34, -0.21) [-0.31 (-0.58, -0.03)]	0.007
Week 22	105	105	3.3 (2.72)			99	99	2.1 (2.06)				
Week 22 chg	105	105	-3.6 (2.63)	-3.37	(0.20)	99	99	-4.2 (2.39)	-4.32	(0.20)	-0.95 (-1.52, -0.39) [-0.38 (-0.66, -0.10)]	0.001
Week 23	105	105	3.2 (2.64)			98	98	2.2 (2.10)				
Week 23 chg	105	105	-3.7 (2.50)	-3.45	(0.20)	98	98	-4.1 (2.51)	-4.25	(0.20)	-0.80 (-1.37, -0.24) [-0.32 (-0.60, -0.04)]	0.005
Week 24	105	105	3.1 (2.55)			96	96	2.1 (1.97)				
Week 24 chg	105	105	-3.8 (2.50)	-3.55	(0.20)	96	96	-4.2 (2.44)	-4.31	(0.20)	-0.76 (-1.33, -0.20) [-0.31 (-0.59, -0.03)]	0.008
Week 25	100	100	2.8 (2.44)			98	98	2.1 (2.06)				
Week 25 chg	100	100	-4.1 (2.45)	-3.73	(0.20)	98	98	-4.2 (2.50)	-4.37	(0.20)	-0.63 (-1.20, -0.07) [-0.26 (-0.54, 0.02)]	0.029
Week 26	98	98	2.9 (2.45)			101	101	2.1 (2.01)				
Week 26 chg	98	98	-4.0 (2.48)	-3.65	(0.20)	101	101	-4.2 (2.50)	-4.35	(0.20)	-0.70 (-1.26, -0.13) [-0.28 (-0.56, -0.00)]	0.016

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7874
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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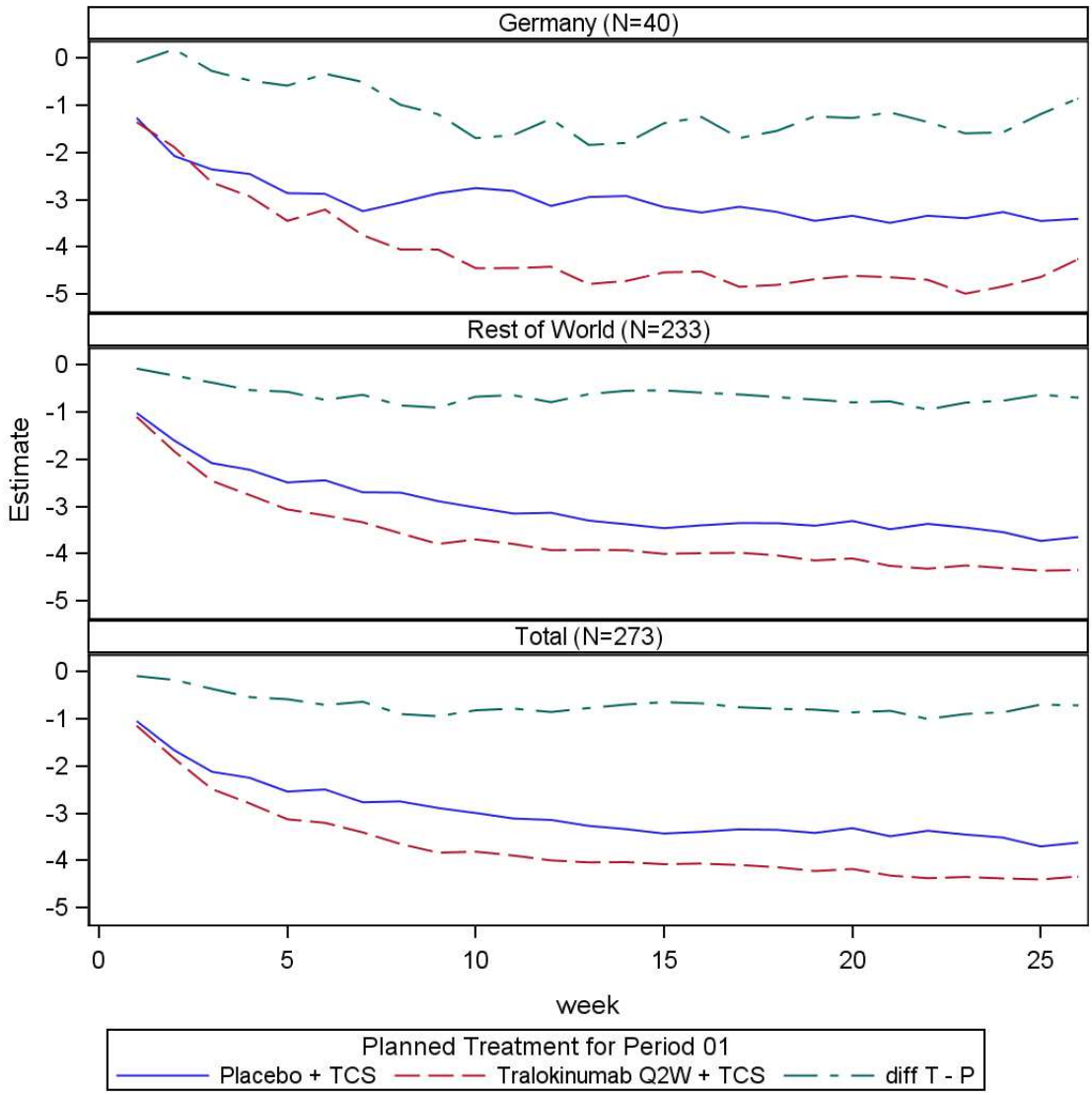
Figure 1.16.418.4.2: Total, Region, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.16.420.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.24 (1.50)		138 -20.9 (16.72)	-21.09 (1.49)	-3.85 (-8.01, 0.31) 0.070 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.30 (1.51)		137 -30.8 (17.25)	-31.04 (1.50)	-4.74 (-8.92, -0.57) 0.026 [-0.27 (-0.50, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.83 (1.51)		134 -34.3 (17.49)	-34.46 (1.50)	-7.63 (-11.8, -3.43) <.001 [-0.42 (-0.66, -0.17)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.66 (1.51)		130 -36.6 (18.48)	-36.77 (1.51)	-8.11 (-12.3, -3.91) <.001 [-0.42 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.81 (1.51)		130 -38.5 (19.49)	-38.57 (1.51)	-7.76 (-12.0, -3.55) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.59 (1.52)		128 -39.5 (18.74)	-39.57 (1.52)	-7.98 (-12.2, -3.76) <.001 [-0.42 (-0.66, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8735
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.420.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 36.0 (19.61)			127 28.3 (17.87)		
Week 14 chg		126 -34.8 (20.31)	-34.25 (1.53)		127 -41.8 (20.11)	-41.39 (1.52)	-7.14 (-11.4, -2.91) <.001 [-0.35 (-0.60, -0.11)]
Week 16		124 36.3 (18.78)			123 27.0 (16.90)		
Week 16 chg		124 -34.7 (19.94)	-33.90 (1.53)		123 -43.3 (19.46)	-42.70 (1.53)	-8.80 (-13.0, -4.55) <.001 [-0.45 (-0.70, -0.19)]
Week 18		116 36.8 (19.98)			115 25.1 (15.97)		
Week 18 chg		116 -34.1 (20.70)	-33.27 (1.55)		115 -44.8 (19.27)	-43.62 (1.55)	-10.36 (-14.7, -6.05) <.001 [-0.52 (-0.78, -0.26)]
Week 20		107 35.7 (19.63)			117 25.6 (16.83)		
Week 20 chg		107 -35.6 (20.01)	-34.07 (1.57)		117 -44.9 (18.80)	-43.48 (1.54)	-9.41 (-13.7, -5.08) <.001 [-0.49 (-0.75, -0.22)]
Week 22		112 35.6 (20.27)			114 23.3 (14.77)		
Week 22 chg		112 -35.5 (20.64)	-34.08 (1.56)		114 -46.8 (19.03)	-45.23 (1.55)	-11.15 (-15.5, -6.83) <.001 [-0.56 (-0.83, -0.30)]
Week 24		112 34.6 (19.86)			117 23.3 (15.61)		
Week 24 chg		112 -36.5 (20.30)	-34.56 (1.56)		117 -46.9 (18.55)	-45.65 (1.54)	-11.09 (-15.4, -6.78) <.001 [-0.57 (-0.84, -0.31)]
Week 26		118 33.1 (18.32)			125 23.8 (16.51)		
Week 26 chg		118 -38.1 (19.21)	-36.22 (1.54)		125 -46.3 (19.60)	-45.94 (1.52)	-9.72 (-14.0, -5.46) <.001 [-0.50 (-0.76, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8735
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.420.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 69.5 (9.23)		22	22 67.2 (6.09)		
Week 2		18 51.9 (14.71)			22 47.3 (12.97)		
Week 2 chg		18 -17.5 (16.40)	-16.56 (4.07)		22 -19.9 (12.07)	-20.51 (3.66)	-3.95 (-15.0, 7.07) 0.476 [-0.28 (-0.90, 0.35)]
Week 4		17 40.7 (17.64)			22 39.0 (14.92)		
Week 4 chg		17 -29.0 (19.85)	-26.78 (4.13)		22 -28.2 (15.45)	-29.07 (3.66)	-2.28 (-13.4, 8.83) 0.683 [-0.13 (-0.76, 0.50)]
Week 6		17 40.9 (21.12)			22 35.6 (14.66)		
Week 6 chg		17 -28.8 (20.82)	-27.14 (4.13)		22 -31.6 (15.37)	-32.18 (3.66)	-5.04 (-16.2, 6.08) 0.368 [-0.28 (-0.92, 0.35)]
Week 8		17 41.8 (21.74)			20 30.5 (11.77)		
Week 8 chg		17 -28.0 (22.06)	-25.96 (4.13)		20 -36.1 (13.71)	-36.75 (3.74)	-10.79 (-22.0, 0.45) 0.060 [-0.60 (-1.26, 0.06)]
Week 10		17 38.6 (21.01)			20 28.9 (12.79)		
Week 10 chg		17 -31.2 (21.41)	-29.31 (4.13)		20 -37.6 (13.89)	-38.17 (3.74)	-8.86 (-20.1, 2.38) 0.120 [-0.50 (-1.16, 0.16)]
Week 12		16 38.7 (22.41)			19 28.4 (17.09)		
Week 12 chg		16 -31.4 (22.26)	-27.81 (4.18)		19 -38.0 (18.55)	-38.84 (3.77)	-11.04 (-22.4, 0.32) 0.057 [-0.54 (-1.22, 0.13)]
Week 14		17 38.5 (22.59)			19 27.3 (10.89)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8735
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.420.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	17	-31.2 (22.25)	-29.35 (4.13)	19	-39.3 (13.44)	-38.60 (3.77)	-9.24 (-20.5, 2.03) 0.106 [-0.51 (-1.17, 0.15)]
Week 16	17	36.6 (23.16)		19	24.9 (9.31)		
Week 16 chg	17	-33.1 (22.89)	-31.35 (4.13)	19	-41.6 (11.31)	-40.84 (3.77)	-9.50 (-20.8, 1.78) 0.097 [-0.54 (-1.20, 0.13)]
Week 18	17	37.7 (24.75)		19	22.1 (11.24)		
Week 18 chg	17	-32.0 (23.76)	-30.00 (4.13)	19	-44.5 (15.29)	-43.92 (3.77)	-13.92 (-25.2, -2.64) 0.016 [-0.71 (-1.38, -0.03)]
Week 20	15	34.7 (24.50)		18	22.5 (10.80)		
Week 20 chg	15	-35.3 (23.50)	-30.73 (4.22)	18	-44.6 (12.55)	-42.79 (3.80)	-12.06 (-23.5, -0.63) 0.039 [-0.66 (-1.36, 0.05)]
Week 22	15	33.8 (16.85)		18	27.8 (12.52)		
Week 22 chg	15	-34.6 (20.28)	-29.41 (4.21)	18	-39.3 (14.10)	-37.66 (3.80)	-8.25 (-19.6, 3.14) 0.153 [-0.48 (-1.18, 0.21)]
Week 24	15	32.5 (16.34)		18	21.5 (11.93)		
Week 24 chg	15	-35.9 (19.04)	-30.78 (4.21)	18	-45.6 (13.14)	-43.76 (3.80)	-12.98 (-24.4, -1.59) 0.026 [-0.81 (-1.52, -0.09)]
Week 26	15	31.7 (17.18)		18	22.4 (14.68)		
Week 26 chg	15	-36.7 (19.80)	-31.60 (4.21)	18	-44.7 (16.20)	-42.92 (3.80)	-11.31 (-22.7, 0.08) 0.051 [-0.63 (-1.33, 0.07)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8735
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.420.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 71.0 (13.32)		116	116 70.7 (12.81)		
Week 2		119 53.6 (18.06)			116 49.7 (19.04)		
Week 2 chg		119 -17.5 (16.08)	-17.27 (1.63)		116 -21.1 (17.50)	-21.26 (1.65)	-3.99 (-8.54, 0.56) 0.085 [-0.24 (-0.49, 0.02)]
Week 4		117 44.3 (18.47)			115 39.2 (18.17)		
Week 4 chg		117 -26.6 (18.30)	-26.11 (1.63)		115 -31.3 (17.59)	-31.49 (1.65)	-5.38 (-9.94, -0.81) 0.021 [-0.30 (-0.56, -0.04)]
Week 6		115 43.8 (18.65)			112 35.8 (17.06)		
Week 6 chg		115 -27.2 (18.98)	-26.77 (1.64)		112 -34.8 (17.89)	-34.91 (1.66)	-8.14 (-12.7, -3.56) <.001 [-0.44 (-0.70, -0.18)]
Week 8		116 41.5 (19.93)			110 33.9 (17.75)		
Week 8 chg		116 -29.2 (19.65)	-28.99 (1.63)		110 -36.7 (19.27)	-36.83 (1.66)	-7.83 (-12.4, -3.25) <.001 [-0.40 (-0.67, -0.14)]
Week 10		114 39.4 (19.88)			110 31.9 (19.02)		
Week 10 chg		114 -31.6 (21.17)	-31.02 (1.64)		110 -38.7 (20.38)	-38.65 (1.66)	-7.63 (-12.2, -3.04) 0.001 [-0.37 (-0.63, -0.10)]
Week 12		112 38.6 (17.67)			109 30.8 (17.81)		
Week 12 chg		112 -32.6 (19.35)	-32.11 (1.65)		109 -39.8 (18.85)	-39.73 (1.67)	-7.63 (-12.2, -3.02) 0.001 [-0.40 (-0.67, -0.13)]
Week 14		109 35.6 (19.19)			108 28.5 (18.87)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8735
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.420.4.1: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	109 -35.3 (20.05)	-34.99 (1.65)	108	108 -42.2 (21.09)	-41.89 (1.67)	-6.89 (-11.5, -2.27) [-0.34 (-0.60, -0.07)]	0.004
Week 16	107	107 36.3 (18.11)		104	104 27.3 (17.95)			
Week 16 chg	107	107 -35.0 (19.53)	-34.31 (1.66)	104	104 -43.6 (20.63)	-42.99 (1.68)	-8.68 (-13.3, -4.04) [-0.43 (-0.71, -0.16)]	<.001
Week 18	99	99 36.7 (19.19)		96	96 25.7 (16.73)			
Week 18 chg	99	99 -34.5 (20.25)	-33.76 (1.68)	96	96 -44.8 (20.03)	-43.54 (1.71)	-9.78 (-14.5, -5.06) [-0.49 (-0.77, -0.20)]	<.001
Week 20	92	92 35.8 (18.88)		99	99 26.1 (17.70)			
Week 20 chg	92	92 -35.6 (19.53)	-34.59 (1.71)	99	99 -45.0 (19.77)	-43.60 (1.70)	-9.00 (-13.7, -4.27) [-0.46 (-0.75, -0.17)]	<.001
Week 22	97	97 35.9 (20.81)		96	96 22.5 (15.06)			
Week 22 chg	97	97 -35.6 (20.80)	-34.77 (1.69)	96	96 -48.2 (19.56)	-46.65 (1.71)	-11.88 (-16.6, -7.15) [-0.59 (-0.88, -0.30)]	<.001
Week 24	97	97 35.0 (20.41)		99	99 23.6 (16.22)			
Week 24 chg	97	97 -36.5 (20.58)	-35.10 (1.69)	99	99 -47.2 (19.42)	-45.97 (1.70)	-10.87 (-15.6, -6.16) [-0.54 (-0.83, -0.26)]	<.001
Week 26	103	103 33.4 (18.55)		107	107 24.0 (16.85)			
Week 26 chg	103	103 -38.3 (19.21)	-36.88 (1.67)	107	107 -46.6 (20.16)	-46.46 (1.67)	-9.58 (-14.2, -4.93) [-0.49 (-0.76, -0.21)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8735
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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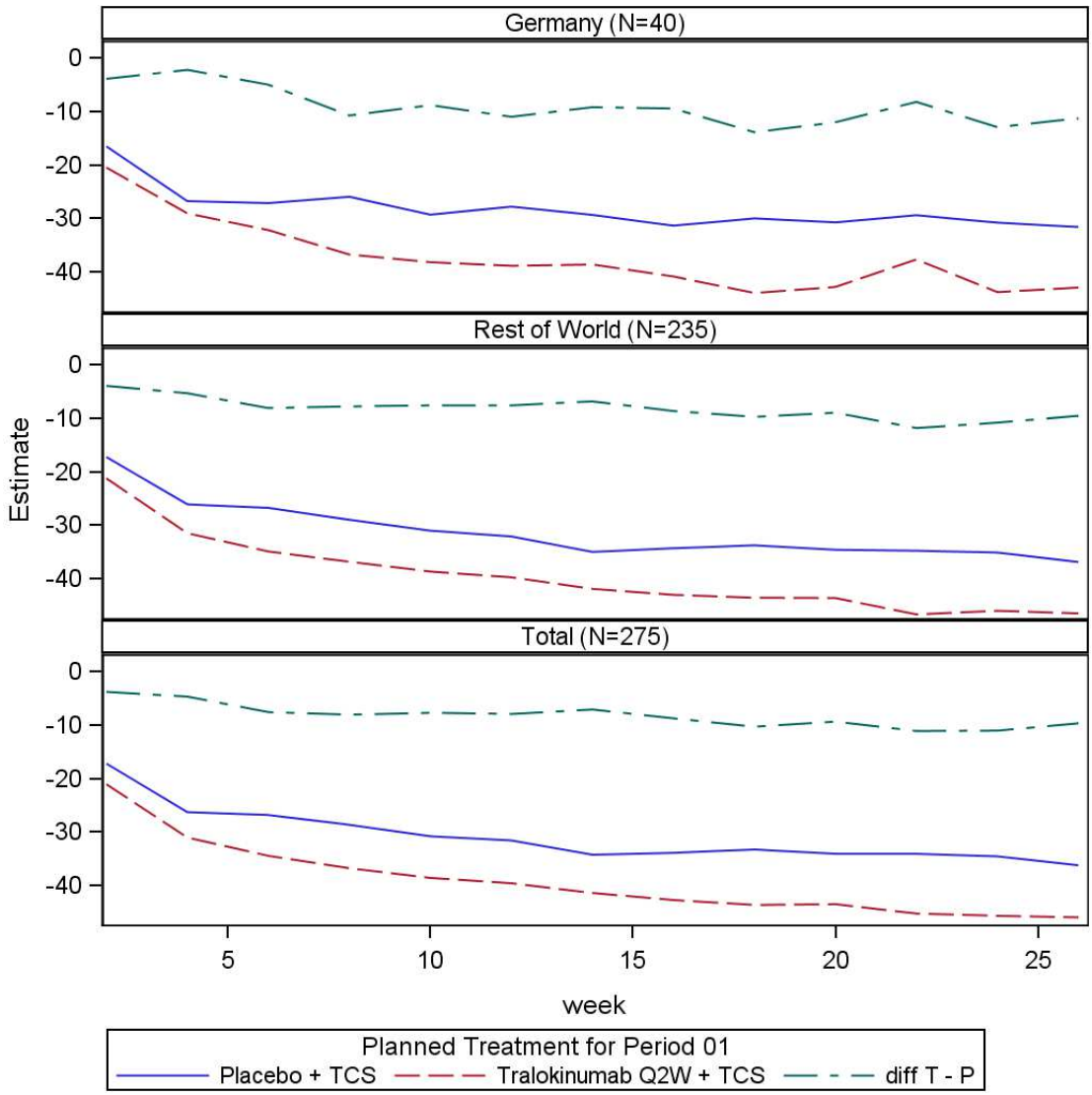
Figure 1.16.420.4.2: Total, Region, change in SCORAD, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.16.422.4.1: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score											
Total											
Baseline	137	134	16.4 (6.33)			138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)				132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.13 (0.44)			132	-7.5 (5.92)	-7.54 (0.44)		-0.41 (-1.63, 0.81) 0.508 [-0.07 (-0.31, 0.17)]
Week 4		130	7.8 (6.27)				135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.30 (0.44)			135	-9.0 (6.32)	-9.13 (0.44)		-0.82 (-2.04, 0.40) 0.185 [-0.13 (-0.37, 0.11)]
Week 6		123	7.3 (6.07)				126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.60 (0.45)			126	-10.0 (6.75)	-9.85 (0.44)		-1.25 (-2.48, -0.01) 0.048 [-0.18 (-0.43, 0.07)]
Week 8		127	6.9 (5.70)				128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.94 (0.44)			128	-10.6 (6.29)	-10.36 (0.44)		-1.41 (-2.64, -0.19) 0.024 [-0.22 (-0.46, 0.03)]
Week 12		123	6.8 (5.89)				124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.29 (0.45)			124	-10.6 (5.77)	-10.55 (0.44)		-1.26 (-2.50, -0.02) 0.046 [-0.19 (-0.44, 0.06)]
Week 16		120	6.5 (5.63)				118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.45)			118	-11.0 (5.99)	-11.14 (0.45)		-1.46 (-2.71, -0.22) 0.022 [-0.23 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3070
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.422.4.1: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 20	102	6.2 (5.67)		111	4.1 (3.92)		
Week 20 chg	102	-9.9 (7.06)	-9.64 (0.46)	111	-11.4 (5.58)	-11.49 (0.45)	-1.85 (-3.13, -0.57) 0.005 [-0.29 (-0.56, -0.02)]
Week 26	110	6.3 (5.26)		116	4.3 (4.31)		
Week 26 chg	110	-10.4 (6.56)	-9.61 (0.46)	116	-11.1 (6.17)	-11.28 (0.45)	-1.67 (-2.93, -0.41) 0.010 [-0.26 (-0.52, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3070
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.422.4.1: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany											
Baseline	18	17	16.0 (7.96)			22	22	16.1 (5.18)			
Week 2		16	9.3 (6.18)				21	9.0 (5.02)			
Week 2 chg		16	-7.4 (8.28)	-7.27	(1.39)		21	-7.2 (4.47)	-7.17	(1.21)	0.11 (-3.60, 3.81) 0.954 [0.02 (-0.63, 0.67)]
Week 4		16	7.6 (5.27)				21	5.5 (5.35)			
Week 4 chg		16	-8.4 (8.82)	-7.88	(1.39)		21	-10.4 (5.34)	-10.57	(1.21)	-2.69 (-6.40, 1.02) 0.152 [-0.38 (-1.04, 0.27)]
Week 6		15	7.4 (6.08)				22	7.0 (7.08)			
Week 6 chg		15	-9.3 (8.56)	-8.38	(1.40)		22	-9.0 (7.32)	-9.08	(1.21)	-0.70 (-4.42, 3.03) 0.709 [-0.09 (-0.75, 0.57)]
Week 8		16	6.9 (4.64)				20	5.6 (6.46)			
Week 8 chg		16	-9.0 (8.49)	-8.50	(1.39)		20	-10.7 (6.25)	-10.16	(1.22)	-1.66 (-5.39, 2.07) 0.376 [-0.23 (-0.89, 0.43)]
Week 12		15	6.4 (4.64)				19	5.2 (4.21)			
Week 12 chg		15	-9.9 (8.48)	-9.05	(1.40)		19	-11.3 (5.79)	-10.56	(1.23)	-1.50 (-5.26, 2.25) 0.426 [-0.21 (-0.89, 0.47)]
Week 16		16	6.9 (5.94)				19	5.0 (5.17)			
Week 16 chg		16	-9.0 (8.91)	-8.51	(1.39)		19	-11.0 (5.79)	-10.47	(1.23)	-1.97 (-5.70, 1.77) 0.296 [-0.27 (-0.93, 0.40)]
Week 20		13	5.8 (5.23)				18	4.3 (3.37)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3070
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.422.4.1: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	13	-10.8 (9.21)	-9.46 (1.43)	18	-11.3 (5.48)	-10.26 (1.24)	-0.80 (-4.62, 3.01) [-0.11 (-0.82, 0.60)]	0.675
Week 26	13	6.2 (4.90)		18	4.9 (4.62)			
Week 26 chg	13	-10.3 (8.66)	-9.07 (1.43)	18	-10.6 (6.68)	-9.59 (1.24)	-0.53 (-4.34, 3.28) [-0.07 (-0.78, 0.64)]	0.782

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3070
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.422.4.1: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	117	16.4 (6.10)			116	115	15.8 (6.78)			
Week 2		115	9.2 (6.54)				111	8.4 (6.38)			
Week 2 chg		115	-7.2 (5.33)	-7.12	(0.47)		111	-7.6 (6.17)	-7.61	(0.47)	-0.49 (-1.80, 0.82) 0.461 [-0.09 (-0.35, 0.18)]
Week 4		114	7.8 (6.42)				114	7.0 (6.09)			
Week 4 chg		114	-8.6 (6.36)	-8.36	(0.47)		114	-8.8 (6.47)	-8.86	(0.47)	-0.50 (-1.81, 0.81) 0.453 [-0.08 (-0.34, 0.18)]
Week 6		108	7.3 (6.10)				104	5.8 (5.50)			
Week 6 chg		108	-8.9 (7.08)	-8.63	(0.47)		104	-10.2 (6.64)	-10.01	(0.48)	-1.38 (-2.71, -0.05) 0.041 [-0.20 (-0.47, 0.07)]
Week 8		111	6.9 (5.86)				108	5.4 (4.86)			
Week 8 chg		111	-9.4 (6.61)	-9.00	(0.47)		108	-10.6 (6.33)	-10.39	(0.48)	-1.39 (-2.71, -0.07) 0.039 [-0.21 (-0.48, 0.05)]
Week 12		108	6.8 (6.06)				105	5.0 (3.89)			
Week 12 chg		108	-9.8 (7.12)	-9.32	(0.47)		105	-10.5 (5.78)	-10.54	(0.48)	-1.22 (-2.55, 0.11) 0.071 [-0.19 (-0.46, 0.08)]
Week 16		104	6.4 (5.61)				99	4.4 (3.60)			
Week 16 chg		104	-10.1 (6.14)	-9.84	(0.48)		99	-10.9 (6.06)	-11.26	(0.49)	-1.42 (-2.76, -0.08) 0.038 [-0.23 (-0.51, 0.04)]
Week 20		89	6.3 (5.76)				93	4.1 (4.03)			

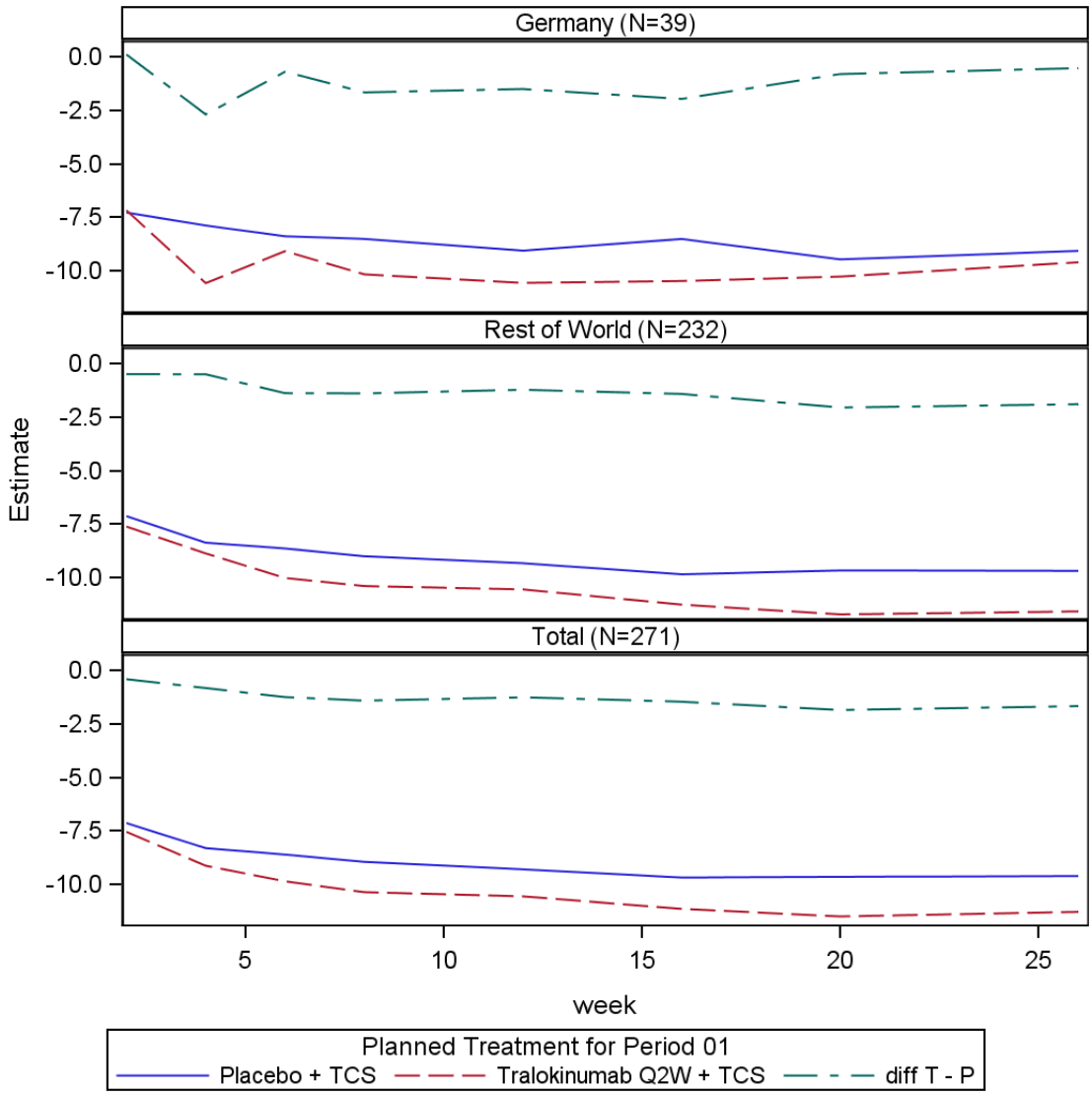
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3070
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.422.4.1: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	89	-9.8 (6.74)	-9.66 (0.49)	93	-11.5 (5.63)	-11.71 (0.49)	-2.05 (-3.42, -0.68) [-0.33 (-0.62, -0.04)]	0.003
Week 26	97	6.3 (5.34)		98	4.2 (4.27)			
Week 26 chg	97	-10.4 (6.29)	-9.68 (0.49)	98	-11.2 (6.10)	-11.57 (0.49)	-1.90 (-3.25, -0.54) [-0.31 (-0.59, -0.02)]	0.006

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3070
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.422.4.2: Total, Region, change in DLQI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.16.423.4.1: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total							
Total							
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)		
Week 2		130 15.1 (6.91)			130 13.5 (6.31)		
Week 2 chg		130 -5.9 (6.29)	-5.97 (0.55)		130 -7.7 (5.43)	-7.67 (0.55)	-1.71 (-3.23, -0.18) 0.029 [-0.29 (-0.53, -0.05)]
Week 4		130 13.8 (7.45)			133 11.6 (6.30)		
Week 4 chg		130 -7.1 (7.56)	-7.11 (0.55)		133 -9.7 (6.02)	-9.53 (0.55)	-2.42 (-3.94, -0.89) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123 13.5 (7.81)			124 10.9 (5.95)		
Week 6 chg		123 -7.2 (8.29)	-7.29 (0.56)		124 -10.6 (6.27)	-10.35 (0.56)	-3.07 (-4.61, -1.52) <.001 [-0.42 (-0.67, -0.17)]
Week 8		127 13.1 (7.02)			126 9.9 (5.79)		
Week 8 chg		127 -7.6 (7.95)	-7.70 (0.55)		126 -11.5 (6.10)	-11.16 (0.55)	-3.46 (-5.00, -1.92) <.001 [-0.49 (-0.74, -0.24)]
Week 12		123 13.0 (7.39)			122 9.2 (5.72)		
Week 12 chg		123 -8.0 (8.26)	-7.91 (0.56)		122 -12.4 (6.20)	-11.78 (0.56)	-3.88 (-5.43, -2.33) <.001 [-0.53 (-0.79, -0.28)]
Week 16		120 13.0 (7.69)			116 9.1 (5.58)		
Week 16 chg		120 -8.0 (8.09)	-8.08 (0.56)		116 -12.2 (6.39)	-11.81 (0.56)	-3.73 (-5.30, -2.17) <.001 [-0.51 (-0.77, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7026
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.423.4.1: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	12.3 (7.64)		109	9.0 (5.60)			
Week 20 chg	102	-8.3 (7.60)	-8.25 (0.58)	109	-12.2 (6.08)	-11.90 (0.57)	-3.65 (-5.25, -2.05) [-0.53 (-0.81, -0.26)]	<.001
Week 26	110	11.8 (7.82)		114	8.2 (5.65)			
Week 26 chg	110	-8.9 (8.23)	-8.77 (0.57)	114	-12.8 (6.59)	-12.64 (0.57)	-3.86 (-5.44, -2.28) [-0.52 (-0.79, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7026
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.423.4.1: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 21.5 (6.18)		22	22 22.5 (4.35)		
Week 2		16 17.0 (7.11)			21 15.2 (5.79)		
Week 2 chg		16 -5.1 (7.32)	-5.12 (1.62)		21 -7.4 (4.35)	-7.24 (1.42)	-2.12 (-6.42, 2.17) 0.328 [-0.37 (-1.02, 0.29)]
Week 4		16 15.8 (8.70)			21 11.7 (5.36)		
Week 4 chg		16 -5.5 (8.07)	-5.72 (1.63)		21 -10.5 (6.04)	-10.38 (1.42)	-4.66 (-8.98, -0.34) 0.035 [-0.67 (-1.34, 0.00)]
Week 6		15 17.3 (8.35)			22 11.8 (6.32)		
Week 6 chg		15 -4.7 (8.57)	-4.64 (1.65)		22 -10.7 (7.19)	-10.42 (1.40)	-5.78 (-10.1, -1.45) 0.010 [-0.74 (-1.42, -0.07)]
Week 8		16 15.7 (8.48)			20 10.2 (5.01)		
Week 8 chg		16 -5.6 (9.10)	-6.00 (1.63)		20 -12.3 (6.10)	-11.70 (1.44)	-5.70 (-10.0, -1.36) 0.011 [-0.75 (-1.43, -0.07)]
Week 12		15 13.8 (8.43)			19 9.0 (5.35)		
Week 12 chg		15 -7.5 (10.42)	-7.51 (1.66)		19 -13.9 (6.10)	-12.79 (1.46)	-5.29 (-9.71, -0.87) 0.020 [-0.64 (-1.33, 0.05)]
Week 16		16 14.4 (8.20)			19 10.3 (6.34)		
Week 16 chg		16 -6.9 (8.93)	-7.30 (1.63)		19 -11.9 (7.29)	-11.13 (1.45)	-3.83 (-8.20, 0.53) 0.084 [-0.47 (-1.15, 0.20)]
Week 20		13 12.4 (8.41)			18 8.6 (4.82)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7026
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.16.423.4.1: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	13	-8.5 (8.14)	-7.71 (1.72)	18	-13.9 (5.67)	-12.66 (1.47)	-4.95 (-9.46, -0.43) [-0.73 (-1.46, 0.01)]	0.032
Week 26	13	12.0 (9.68)		18	8.1 (4.84)			
Week 26 chg	13	-9.6 (8.36)	-8.86 (1.71)	18	-14.3 (5.36)	-13.17 (1.47)	-4.32 (-8.82, 0.18) [-0.64 (-1.37, 0.09)]	0.060

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7026
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.423.4.1: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World												
Baseline	119	117	20.8 (5.67)			116	113	21.0 (5.25)				
Week 2		114	14.9 (6.88)				109	13.2 (6.38)				
Week 2 chg		114	-6.0 (6.16)	-6.09	(0.59)		109	-7.8 (5.62)	-7.76	(0.60)	-1.67 (-3.32, -0.03) [-0.28 (-0.55, -0.02)]	0.046
Week 4		114	13.5 (7.26)				112	11.6 (6.49)				
Week 4 chg		114	-7.3 (7.49)	-7.30	(0.59)		112	-9.5 (6.03)	-9.37	(0.59)	-2.07 (-3.71, -0.43) [-0.30 (-0.57, -0.04)]	0.014
Week 6		108	13.0 (7.62)				102	10.7 (5.89)				
Week 6 chg		108	-7.5 (8.23)	-7.66	(0.59)		102	-10.6 (6.09)	-10.36	(0.61)	-2.70 (-4.37, -1.03) [-0.37 (-0.64, -0.10)]	0.002
Week 8		111	12.7 (6.75)				106	9.9 (5.95)				
Week 8 chg		111	-7.9 (7.78)	-7.94	(0.59)		106	-11.4 (6.12)	-11.07	(0.60)	-3.13 (-4.79, -1.48) [-0.45 (-0.72, -0.18)]	<.001
Week 12		108	12.9 (7.27)				103	9.3 (5.81)				
Week 12 chg		108	-8.1 (7.97)	-7.99	(0.59)		103	-12.1 (6.20)	-11.59	(0.61)	-3.60 (-5.27, -1.93) [-0.50 (-0.78, -0.23)]	<.001
Week 16		104	12.8 (7.62)				97	8.8 (5.42)				
Week 16 chg		104	-8.2 (7.99)	-8.19	(0.60)		97	-12.3 (6.24)	-11.96	(0.61)	-3.77 (-5.46, -2.09) [-0.52 (-0.81, -0.24)]	<.001
Week 20		89	12.3 (7.58)				91	9.0 (5.76)				

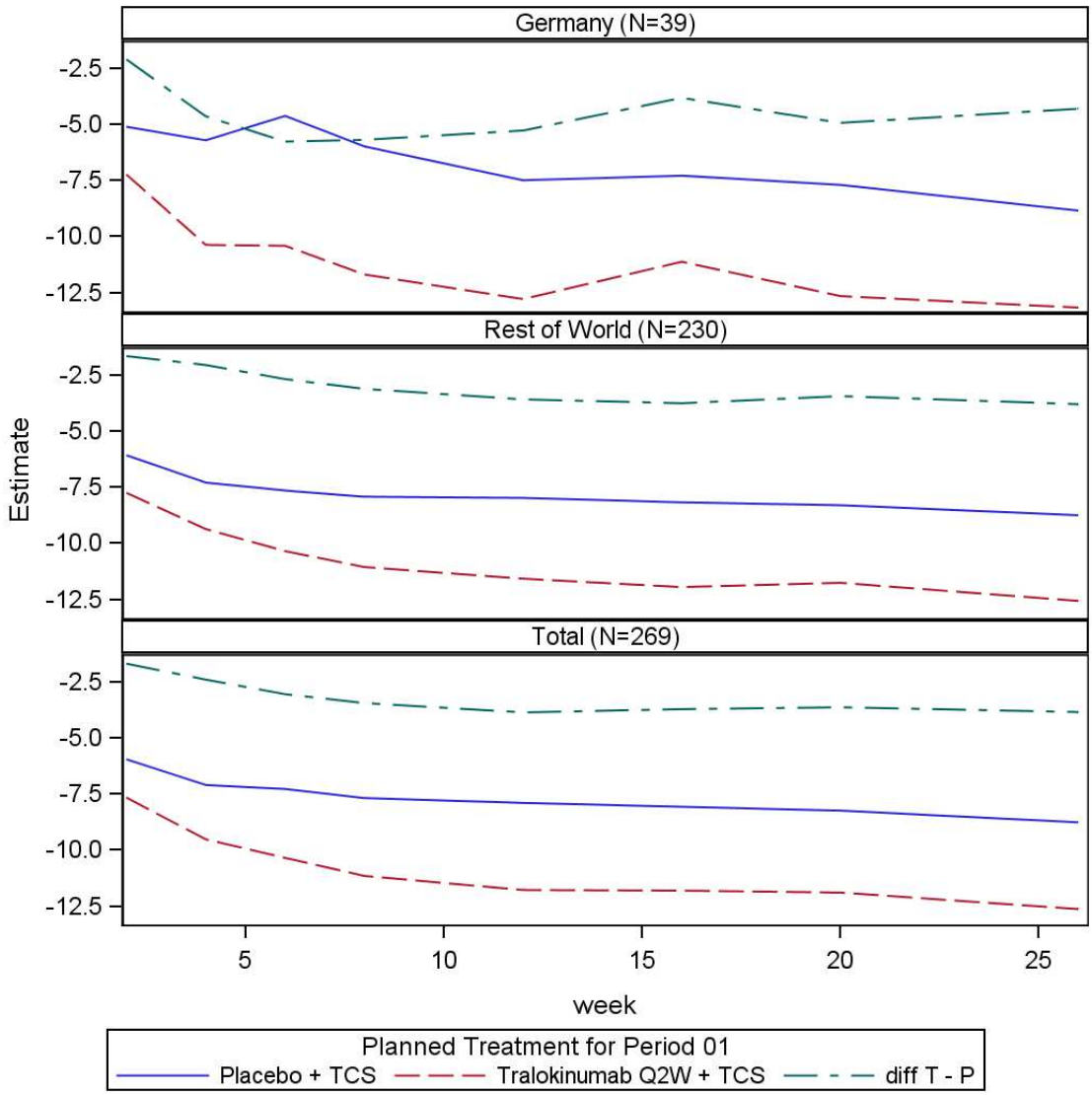
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7026
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.423.4.1: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	89	-8.2 (7.57)	-8.31 (0.62)	91	-11.9 (6.13)	-11.77 (0.62)	-3.46 (-5.19, -1.73) [-0.50 (-0.80, -0.21)]	<.001
Week 26	97	11.8 (7.60)		96	8.3 (5.81)			
Week 26 chg	97	-8.8 (8.25)	-8.76 (0.61)	96	-12.6 (6.78)	-12.57 (0.62)	-3.81 (-5.51, -2.11) [-0.50 (-0.79, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7026
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.16.423.4.2: Total, Region, change in POEM, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.16.428.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.41 (0.22)		138 -2.8 (2.87)	-2.87 (0.22)	-0.45 (-1.08, 0.17) 0.153 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.23 (0.23)		137 -3.8 (2.99)	-3.80 (0.22)	-0.58 (-1.20, 0.05) 0.071 [-0.18 (-0.42, 0.06)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.15 (0.23)		134 -4.1 (2.81)	-4.07 (0.23)	-0.92 (-1.55, -0.29) 0.004 [-0.30 (-0.54, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.50 (0.23)		130 -4.4 (2.91)	-4.34 (0.23)	-0.84 (-1.47, -0.21) 0.009 [-0.27 (-0.51, -0.03)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.65 (0.23)		130 -4.5 (2.93)	-4.46 (0.23)	-0.81 (-1.44, -0.18) 0.012 [-0.26 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.73 (0.23)		128 -4.6 (2.96)	-4.55 (0.23)	-0.83 (-1.46, -0.19) 0.011 [-0.26 (-0.51, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4694
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.428.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	126	2.8 (2.94)		127	2.3 (2.60)			
Week 14 chg	126	-4.0 (3.48)	-3.88 (0.23)	127	-4.4 (3.07)	-4.33 (0.23)	-0.45 (-1.09, 0.18) [-0.14 (-0.38, 0.11)]	0.161
Week 16	124	2.7 (2.77)		123	1.9 (2.39)			
Week 16 chg	124	-4.1 (3.25)	-3.93 (0.23)	123	-4.7 (2.92)	-4.64 (0.23)	-0.72 (-1.36, -0.08) [-0.23 (-0.48, 0.02)]	0.027

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4694
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.428.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 7.1 (2.27)		22	22 6.7 (2.09)		
Week 2		18 4.4 (2.95)			22 3.4 (2.02)		
Week 2 chg		18 -2.7 (3.77)	-2.52 (0.63)		22 -3.3 (2.06)	-3.38 (0.57)	-0.86 (-2.58, 0.85) 0.318 [-0.29 (-0.92, 0.33)]
Week 4		17 3.2 (2.88)			22 2.8 (2.64)		
Week 4 chg		17 -3.9 (3.51)	-3.58 (0.64)		22 -3.9 (2.51)	-3.99 (0.57)	-0.40 (-2.13, 1.33) 0.645 [-0.13 (-0.77, 0.50)]
Week 6		17 3.6 (3.12)			22 2.4 (2.60)		
Week 6 chg		17 -3.5 (3.57)	-3.19 (0.64)		22 -4.3 (2.41)	-4.38 (0.57)	-1.20 (-2.92, 0.53) 0.172 [-0.40 (-1.04, 0.24)]
Week 8		17 3.8 (3.20)			20 1.7 (2.19)		
Week 8 chg		17 -3.3 (3.69)	-2.97 (0.64)		20 -5.0 (2.43)	-4.99 (0.58)	-2.02 (-3.76, -0.28) 0.024 [-0.66 (-1.32, 0.00)]
Week 10		17 3.0 (2.81)			20 1.3 (2.17)		
Week 10 chg		17 -4.1 (3.73)	-3.65 (0.64)		20 -5.3 (2.99)	-5.41 (0.58)	-1.75 (-3.50, -0.01) 0.048 [-0.52 (-1.18, 0.13)]
Week 12		16 3.3 (3.11)			19 1.5 (2.20)		
Week 12 chg		16 -3.7 (3.79)	-3.30 (0.65)		19 -5.2 (2.93)	-5.17 (0.59)	-1.87 (-3.62, -0.11) 0.038 [-0.56 (-1.24, 0.12)]
Week 14		17 3.6 (3.50)			19 1.3 (1.49)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4694
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.428.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	17	-3.5 (4.17)	-3.10 (0.64)	19	-5.2 (2.35)	-5.32 (0.59)	-2.22 (-3.97, -0.47) [-0.67 (-1.34, 0.01)]	0.014
Week 16	17	3.2 (3.13)		19	1.4 (1.88)			
Week 16 chg	17	-3.9 (3.52)	-3.53 (0.64)	19	-5.1 (2.35)	-5.14 (0.59)	-1.61 (-3.36, 0.14) [-0.54 (-1.21, 0.12)]	0.070

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4694
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.428.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 6.7 (2.20)		116	116 6.7 (2.42)		
Week 2		119 4.3 (2.73)			116 3.9 (2.83)		
Week 2 chg		119 -2.4 (2.87)	-2.39 (0.24)		116 -2.7 (2.99)	-2.77 (0.25)	-0.39 (-1.06, 0.29) 0.263 [-0.13 (-0.39, 0.12)]
Week 4		117 3.5 (2.74)			115 2.9 (2.70)		
Week 4 chg		117 -3.2 (3.27)	-3.17 (0.24)		115 -3.7 (3.08)	-3.77 (0.25)	-0.60 (-1.28, 0.08) 0.085 [-0.19 (-0.45, 0.07)]
Week 6		115 3.5 (2.86)			112 2.6 (2.58)		
Week 6 chg		115 -3.2 (3.28)	-3.14 (0.24)		112 -4.1 (2.89)	-4.01 (0.25)	-0.87 (-1.55, -0.19) 0.013 [-0.28 (-0.54, -0.02)]
Week 8		116 3.1 (2.61)			110 2.4 (2.51)		
Week 8 chg		116 -3.6 (3.25)	-3.58 (0.24)		110 -4.3 (2.99)	-4.22 (0.25)	-0.65 (-1.33, 0.04) 0.064 [-0.21 (-0.47, 0.05)]
Week 10		114 3.0 (2.79)			110 2.3 (2.60)		
Week 10 chg		114 -3.7 (3.34)	-3.64 (0.24)		110 -4.3 (2.90)	-4.29 (0.25)	-0.66 (-1.34, 0.03) 0.060 [-0.21 (-0.47, 0.05)]
Week 12		112 2.9 (2.62)			109 2.2 (2.52)		
Week 12 chg		112 -3.9 (3.32)	-3.78 (0.25)		109 -4.5 (2.97)	-4.45 (0.25)	-0.66 (-1.35, 0.02) 0.058 [-0.21 (-0.47, 0.05)]
Week 14		109 2.6 (2.85)			108 2.5 (2.71)		

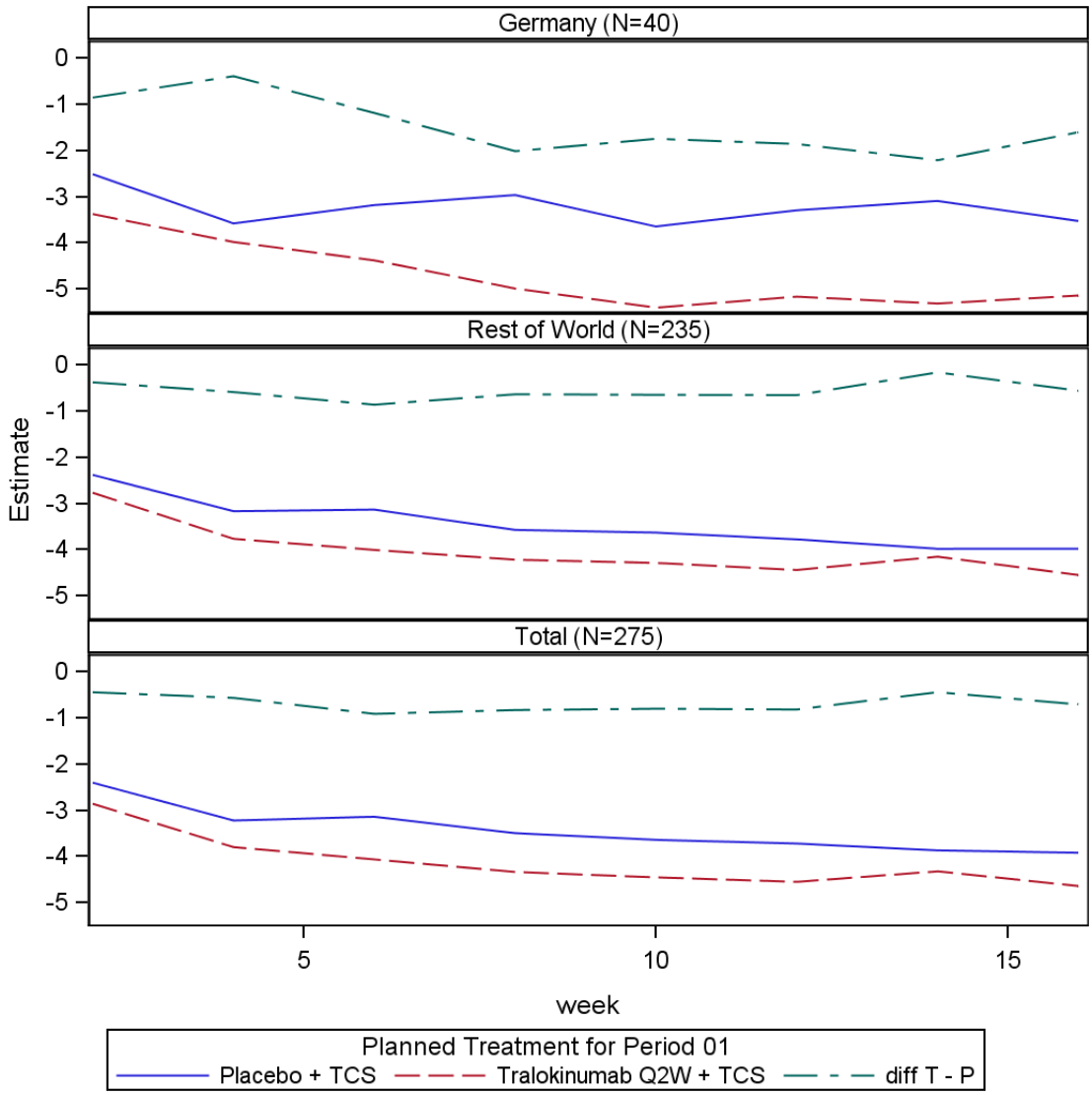
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4694
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.428.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	-4.1 (3.37)	-3.99 (0.25)	108	-4.2 (3.16)	-4.16 (0.25)	-0.17 (-0.86, 0.52) [-0.05 (-0.32, 0.21)]	0.627
Week 16	107	2.6 (2.72)		104	2.0 (2.47)			
Week 16 chg	107	-4.1 (3.23)	-3.99 (0.25)	104	-4.6 (3.02)	-4.55 (0.25)	-0.57 (-1.26, 0.13) [-0.18 (-0.45, 0.09)]	0.108

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4694
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.428.4.2: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.16.429.4.1: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.80 (1.50)		133	17.3 (19.49)	18.41 (1.49)	2.61 (-1.55, 6.77) 0.219 [0.13 (-0.12, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.37 (1.51)		126	18.4 (21.17)	19.36 (1.51)	2.99 (-1.23, 7.20) 0.165 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.37 (1.53)		122	18.7 (21.48)	19.47 (1.53)	2.11 (-2.15, 6.37) 0.332 [0.09 (-0.16, 0.35)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.72 (1.54)		116	17.7 (22.49)	19.74 (1.55)	5.02 (0.71, 9.33) 0.022 [0.20 (-0.05, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9041
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.429.4.1: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 46.9 (24.54)		22	22 47.8 (17.23)		
Week 4		17 70.6 (18.50)			21 69.8 (16.86)		
Week 4 chg		17 23.8 (25.95)	22.72 (4.74)		21 22.2 (22.63)	21.86 (4.21)	-0.86 (-13.5, 11.83) 0.893 [-0.04 (-0.67, 0.60)]
Week 8		16 72.4 (17.05)			20 73.6 (16.72)		
Week 8 chg		16 24.5 (27.97)	22.81 (4.83)		20 24.9 (25.15)	24.28 (4.30)	1.46 (-11.5, 14.42) 0.822 [0.06 (-0.60, 0.71)]
Week 12		15 71.5 (20.08)			19 75.8 (16.85)		
Week 12 chg		15 24.5 (29.22)	21.95 (4.92)		19 27.4 (23.21)	26.32 (4.37)	4.37 (-8.80, 17.53) 0.510 [0.17 (-0.51, 0.85)]
Week 16		16 66.4 (25.09)			19 75.5 (19.22)		
Week 16 chg		16 18.5 (40.28)	16.77 (4.83)		19 25.7 (27.04)	25.21 (4.37)	8.43 (-4.60, 21.47) 0.201 [0.25 (-0.42, 0.92)]

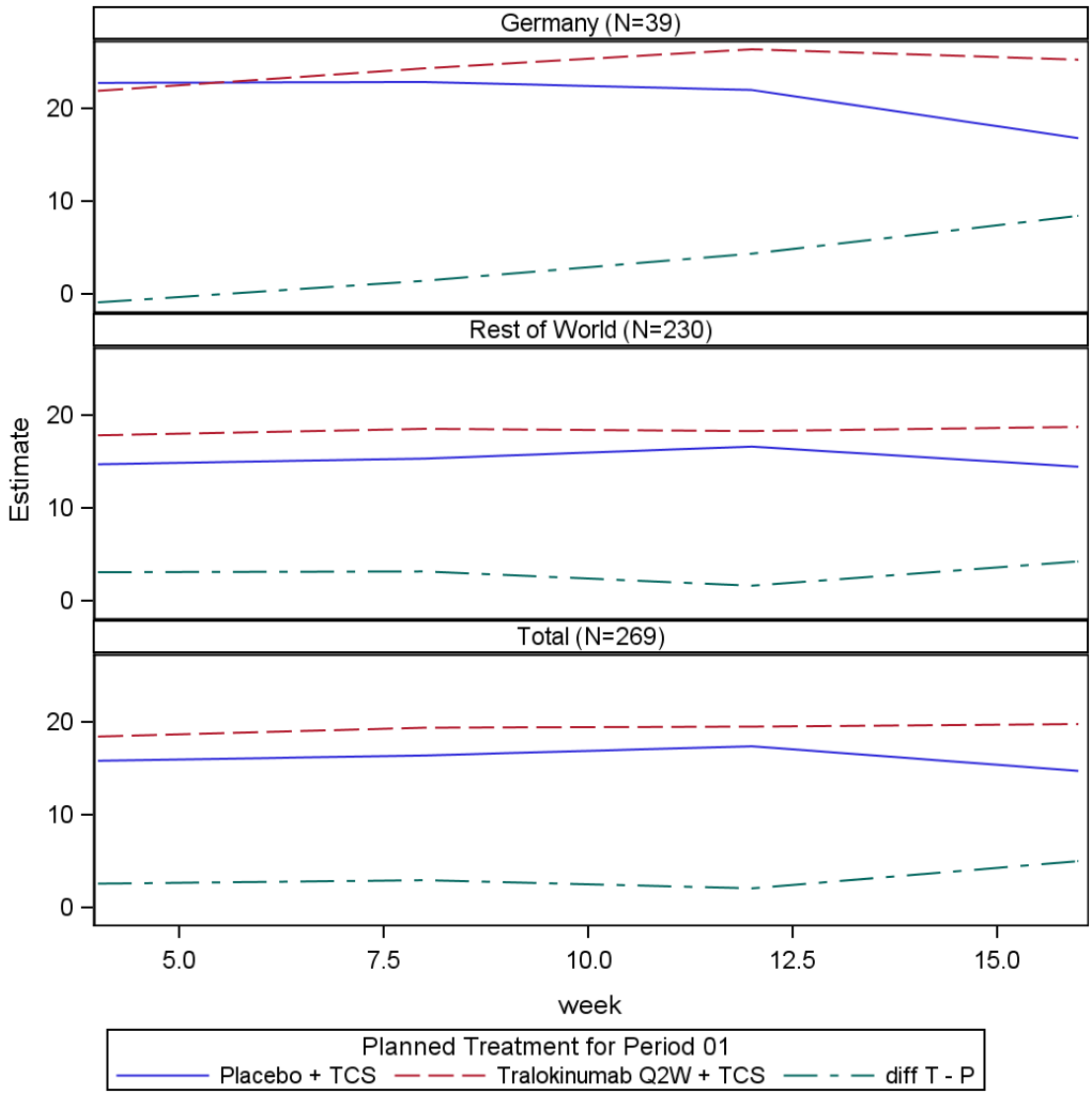
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9041
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.429.4.1: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World										
Baseline	119	117	53.3 (21.57)		116	113	58.3 (20.00)			
Week 4		114	69.4 (17.56)			112	74.6 (16.69)			
Week 4 chg		114	16.4 (21.13)	14.70 (1.57)		112	16.4 (18.82)	17.81 (1.59)	3.11 (-1.31, 7.52) [0.16 (-0.11, 0.42)]	0.167
Week 8		111	70.8 (19.03)			106	75.4 (16.21)			
Week 8 chg		111	17.3 (24.65)	15.32 (1.58)		106	17.2 (20.24)	18.51 (1.62)	3.19 (-1.28, 7.66) [0.14 (-0.13, 0.41)]	0.161
Week 12		108	71.1 (19.27)			103	75.3 (15.85)			
Week 12 chg		108	18.3 (22.07)	16.60 (1.60)		103	17.1 (20.87)	18.26 (1.63)	1.66 (-2.85, 6.17) [0.08 (-0.19, 0.35)]	0.469
Week 16		104	69.6 (21.38)			97	75.7 (16.65)			
Week 16 chg		104	16.4 (24.28)	14.44 (1.61)		97	16.1 (21.29)	18.71 (1.66)	4.27 (-0.31, 8.85) [0.19 (-0.09, 0.46)]	0.068

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9041
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.429.4.2: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.16.430.4.1: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.83 (1.52)		133	17.3 (19.49)	18.45 (1.50)	2.62 (-1.59, 6.82) 0.222 [0.13 (-0.11, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.39 (1.53)		126	18.4 (21.17)	19.38 (1.53)	2.99 (-1.26, 7.24) 0.168 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.49 (1.54)		122	18.7 (21.48)	19.49 (1.54)	1.99 (-2.30, 6.29) 0.362 [0.09 (-0.16, 0.34)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.83 (1.55)		116	17.7 (22.49)	19.65 (1.57)	4.82 (0.48, 9.16) 0.030 [0.19 (-0.06, 0.45)]
Week 20		103	72.7 (20.07)			108	77.3 (14.52)		
Week 20 chg		103	19.3 (25.56)	17.99 (1.61)		108	21.6 (20.57)	21.18 (1.59)	3.20 (-1.26, 7.65) 0.159 [0.14 (-0.13, 0.41)]
Week 26		113	72.4 (20.84)			116	76.4 (17.02)		
Week 26 chg		113	20.5 (25.83)	17.77 (1.58)		116	19.5 (21.18)	20.31 (1.56)	2.53 (-1.84, 6.90) 0.256 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9435
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.430.4.1: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany											
Baseline	18	17	46.9 (24.54)			22	22	47.8 (17.23)			
Week 4		17	70.6 (18.50)				21	69.8 (16.86)			
Week 4 chg		17	23.8 (25.95)	22.70	(4.68)		21	22.2 (22.63)	21.88	(4.16)	-0.81 (-13.3, 11.71) 0.897 [-0.03 (-0.67, 0.61)]
Week 8		16	72.4 (17.05)				20	73.6 (16.72)			
Week 8 chg		16	24.5 (27.97)	22.74	(4.77)		20	24.9 (25.15)	24.24	(4.24)	1.50 (-11.3, 14.28) 0.815 [0.06 (-0.60, 0.71)]
Week 12		15	71.5 (20.08)				19	75.8 (16.85)			
Week 12 chg		15	24.5 (29.22)	21.83	(4.85)		19	27.4 (23.21)	26.27	(4.30)	4.45 (-8.51, 17.40) 0.496 [0.17 (-0.51, 0.85)]
Week 16		16	66.4 (25.09)				19	75.5 (19.22)			
Week 16 chg		16	18.5 (40.28)	16.70	(4.77)		19	25.7 (27.04)	25.14	(4.30)	8.44 (-4.41, 21.29) 0.194 [0.25 (-0.42, 0.92)]
Week 20		13	70.9 (22.72)				18	77.6 (15.45)			
Week 20 chg		13	24.8 (39.57)	19.85	(5.02)		18	27.9 (22.29)	26.47	(4.36)	6.62 (-6.67, 19.91) 0.324 [0.22 (-0.50, 0.93)]
Week 26		14	74.1 (18.12)				18	76.3 (13.45)			
Week 26 chg		14	28.7 (31.18)	24.59	(4.93)		18	26.6 (24.12)	25.08	(4.36)	0.49 (-12.7, 13.65) 0.941 [0.02 (-0.68, 0.72)]

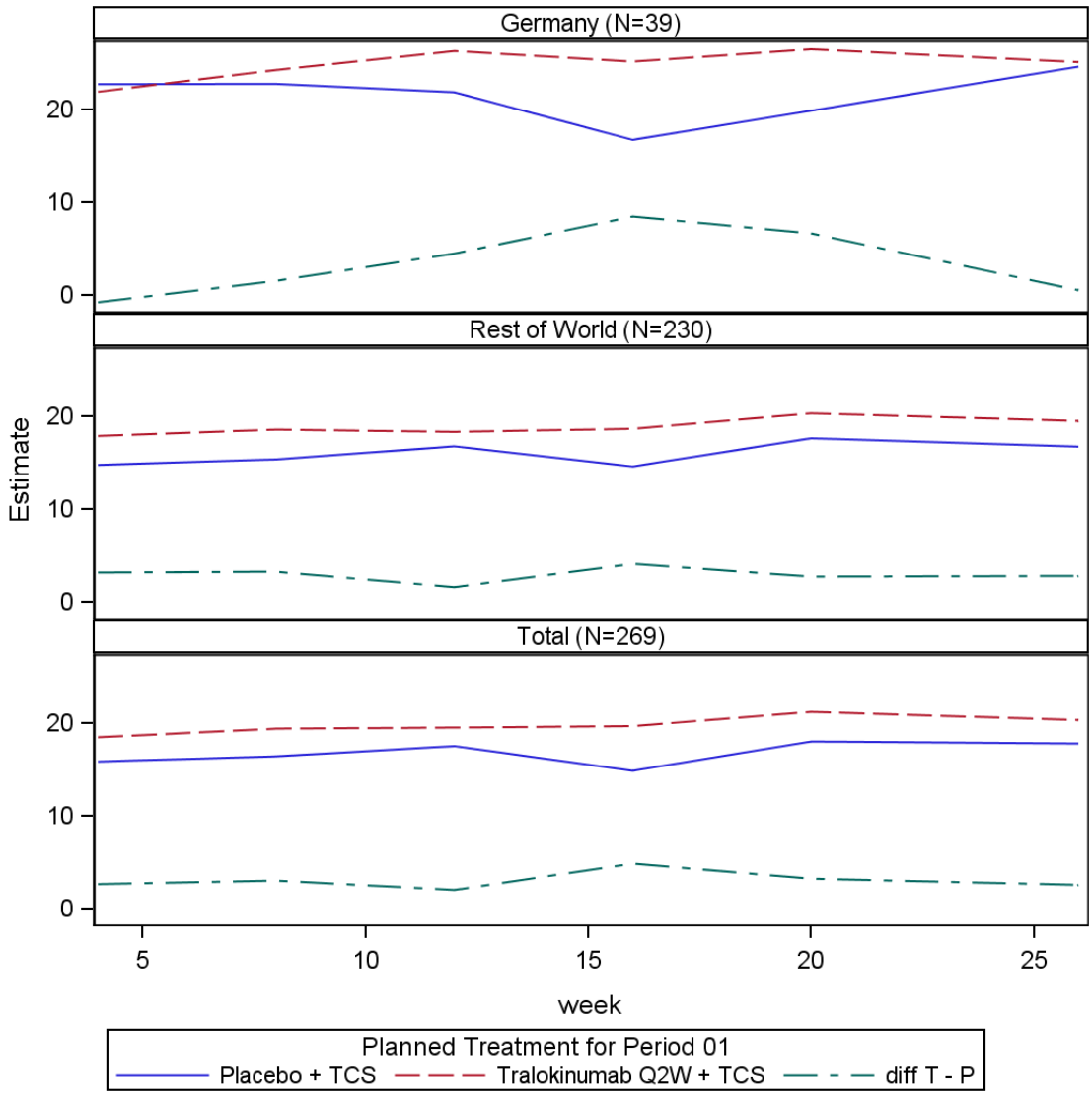
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9435
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.430.4.1: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World									
Baseline	119	117	53.3 (21.57)		116	113	58.3 (20.00)		
Week 4		114	69.4 (17.56)			112	74.6 (16.69)		
Week 4 chg		114	16.4 (21.13)	14.73 (1.59)		112	16.4 (18.82)	17.86 (1.61)	3.13 (-1.35, 7.61) 0.170 [0.16 (-0.10, 0.42)]
Week 8		111	70.8 (19.03)			106	75.4 (16.21)		
Week 8 chg		111	17.3 (24.65)	15.33 (1.60)		106	17.2 (20.24)	18.54 (1.64)	3.21 (-1.32, 7.73) 0.164 [0.14 (-0.12, 0.41)]
Week 12		108	71.1 (19.27)			103	75.3 (15.85)		
Week 12 chg		108	18.3 (22.07)	16.74 (1.62)		103	17.1 (20.87)	18.30 (1.65)	1.55 (-3.01, 6.12) 0.504 [0.07 (-0.20, 0.34)]
Week 16		104	69.6 (21.38)			97	75.7 (16.65)		
Week 16 chg		104	16.4 (24.28)	14.57 (1.63)		97	16.1 (21.29)	18.63 (1.68)	4.06 (-0.57, 8.69) 0.086 [0.18 (-0.10, 0.45)]
Week 20		90	73.0 (19.79)			90	77.2 (14.41)		
Week 20 chg		90	18.5 (23.07)	17.60 (1.69)		90	20.3 (20.10)	20.29 (1.71)	2.68 (-2.05, 7.42) 0.266 [0.12 (-0.17, 0.42)]
Week 26		99	72.2 (21.27)			98	76.4 (17.65)		
Week 26 chg		99	19.4 (24.96)	16.71 (1.66)		98	18.2 (20.46)	19.47 (1.67)	2.76 (-1.89, 7.41) 0.244 [0.12 (-0.16, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9435
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.16.430.4.2: Total, Region, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.16.431.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)									
Total									
Baseline	137	136	6.9 (1.64)		138	137	6.3 (2.11)		
Week 26		117	2.9 (2.55)			122	2.1 (2.00)		
Week 26 chg		116	-4.0 (2.53)	-3.74 (0.21)		121	-4.1 (2.47)	-4.34 (0.20)	-0.60 (-1.17, -0.03) 0.040 [-0.24 (-0.50, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7382
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.431.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 7.3 (1.71)		22	22 6.1 (1.80)		
Week 26		15 3.5 (2.91)			17 1.9 (1.82)		
Week 26 chg		15 -3.8 (3.03)	-3.21 (0.67)		17 -4.0 (2.42)	-4.56 (0.64)	-1.36 (-3.36, 0.64) 0.176 [-0.50 (-1.20, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7382
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.431.4.1: Total, Region, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	119	118 6.8 (1.63)		116	115 6.3 (2.17)			
Week 26		102 2.8 (2.49)			105 2.1 (2.04)			
Week 26 chg		101 -4.0 (2.46)	-3.80 (0.22)		104 -4.1 (2.49)	-4.33 (0.21)	-0.53 (-1.13, 0.08) [-0.21 (-0.49, 0.06)]	0.088

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7382
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.434.4.1: Total, Region, SCORAD 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	21 (15.2)	11.7 (5.02;18.46)	4.3 (1.66;10.96)	5.0 (1.80;13.99)	0.0009	0.2179
Placebo + TCS	137	5 (3.6)					
Germany							
Tralokinumab Q2W + TCS	22	1 (4.5)	-0.3 (-14.5;13.84)	0.9 (0.05;16.35)	0.9 (0.06;15.64)	0.9668	
Placebo + TCS	18	1 (5.6)					
Rest of World							
Tralokinumab Q2W + TCS	116	20 (17.2)	14.2 (6.61;21.77)	5.3 (1.87;15.09)	6.4 (2.08;19.83)	0.0003	
Placebo + TCS	119	4 (3.4)					

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. Treatment policy estimand: Missing values at Week 26 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

Table 1.16.437.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss										
Total										
Baseline	137	137	6.7 (2.21)		138	138	6.7 (2.36)			
Week 26		121	2.5 (2.71)			127	1.6 (2.07)			
Week 26 chg		121	-4.4 (3.09)	-4.30 (0.21)		127	-5.0 (2.78)	-5.09 (0.21)	-0.78 (-1.37, -0.20) [-0.27 (-0.52, -0.02)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4205
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.437.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany											
Baseline	18	18	7.1 (2.27)			22	22	6.7 (2.09)			
Week 26		16	3.1 (3.18)				18	1.3 (1.61)			
Week 26 chg		16	-3.9 (3.31)	-3.64	(0.62)		18	-5.1 (2.14)	-5.33	(0.59)	-1.69 (-3.45, 0.07) 0.059 [-0.62 (-1.30, 0.07)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4205
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.437.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World								
Baseline	119	119 6.7 (2.20)		116	116 6.7 (2.42)			
Week 26		105 2.4 (2.64)			109 1.7 (2.13)			
Week 26 chg		105 -4.5 (3.06)	-4.39 (0.23)		109 -4.9 (2.88)	-5.06 (0.22)	-0.66 (-1.30, -0.03) [-0.22 (-0.49, 0.05)]	0.040

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4205
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.438.4.1: Total, Region, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 26		121 33.4 (18.31)			127 24.1 (16.65)		
Week 26 chg		121 -37.9 (19.30)	-37.26 (1.53)		127 -45.9 (19.70)	-46.62 (1.50)	-9.36 (-13.6, -5.13) <.001 [-0.48 (-0.73, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8426
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.438.4.1: Total, Region, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 69.5 (9.23)		22	22 67.2 (6.09)		
Week 26		16 33.7 (18.49)			18 22.4 (14.68)		
Week 26 chg		16 -34.5 (21.16)	-33.55 (4.21)		18 -44.7 (16.20)	-45.27 (4.02)	-11.72 (-23.8, 0.32) 0.056 [-0.63 (-1.32, 0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8426
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.438.4.1: Total, Region, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 71.0 (13.32)		116	116 70.7 (12.81)		
Week 26		105 33.3 (18.37)			109 24.4 (17.00)		
Week 26 chg		105 -38.4 (19.05)	-37.74 (1.66)		109 -46.1 (20.27)	-46.90 (1.63)	-9.17 (-13.8, -4.57) <.001 [-0.47 (-0.74, -0.19)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8426
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.439.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)											
Total											
Baseline	137	136	7.5 (1.37)			138	137	7.3 (1.45)			
Week 26		117	3.9 (2.53)				122	3.0 (1.94)			
Week 26 chg		116	-3.6 (2.55)	-3.47	(0.20)		121	-4.2 (2.13)	-4.31	(0.20)	-0.84 (-1.41, -0.28) 0.004 [-0.36 (-0.62, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8656
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.439.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 7.9 (1.35)		22	22 7.1 (1.41)		
Week 26		15 4.3 (2.89)			17 3.0 (1.86)		
Week 26 chg		15 -3.5 (3.26)	-3.17 (0.67)		17 -4.0 (1.69)	-4.29 (0.63)	-1.12 (-3.08, 0.84) 0.250 [-0.44 (-1.14, 0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8656
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.439.4.1: Total, Region, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	118	7.4 (1.37)			116	115	7.3 (1.47)			
Week 26		102	3.9 (2.48)				105	3.0 (1.97)			
Week 26 chg		101	-3.6 (2.45)	-3.51	(0.22)		104	-4.3 (2.19)	-4.33	(0.21)	-0.82 (-1.42, -0.22) 0.008 [-0.35 (-0.63, -0.08)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8656
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.440.4.1: Total, Region, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
POEM Total								
Total								
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)			
Week 26		115 11.9 (7.89)			119 8.4 (5.90)			
Week 26 chg		113 -8.7 (8.23)	-8.90 (0.62)		116 -12.7 (6.64)	-12.63 (0.62)	-3.73 (-5.46, -2.00) [-0.50 (-0.76, -0.24)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7379
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.440.4.1: Total, Region, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 21.5 (6.18)		22	22 22.5 (4.35)		
Week 26		15 12.4 (10.10)			18 8.1 (4.84)		
Week 26 chg		14 -8.6 (8.93)	-8.66 (1.80)		18 -14.3 (5.36)	-14.47 (1.61)	-5.80 (-10.8, -0.83) 0.024 [-0.81 (-1.54, -0.09)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7379
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.440.4.1: Total, Region, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	117 20.8 (5.67)		116	113 21.0 (5.25)		
Week 26		100 11.8 (7.56)			101 8.5 (6.09)		
Week 26 chg		99 -8.7 (8.18)	-8.89 (0.67)		98 -12.4 (6.83)	-12.34 (0.67)	-3.46 (-5.34, -1.58) <.001 [-0.46 (-0.74, -0.18)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7379
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.442.4.1: Total, Region, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 26		115 6.2 (5.20)			119 4.4 (4.42)		
Week 26 chg		113 -10.3 (6.57)	-10.01 (0.42)		118 -11.2 (6.17)	-11.51 (0.41)	-1.50 (-2.66, -0.34) 0.011 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8847
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.442.4.1: Total, Region, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 16.0 (7.96)		22	22 16.1 (5.18)		
Week 26		15 6.3 (4.69)			18 4.9 (4.62)		
Week 26 chg		14 -9.6 (8.69)	-9.20 (1.21)		18 -10.6 (6.68)	-11.20 (1.08)	-2.00 (-5.35, 1.35) 0.232 [-0.26 (-0.96, 0.44)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8847
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.442.4.1: Total, Region, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	117	16.4 (6.10)			116	115	15.8 (6.78)			
Week 26		100	6.2 (5.30)				101	4.3 (4.40)			
Week 26 chg		99	-10.4 (6.26)	-10.10	(0.45)		100	-11.3 (6.10)	-11.59	(0.44)	-1.48 (-2.73, -0.24) 0.020 [-0.24 (-0.52, 0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8847
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.443.4.1: Total, Region, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 26		121 9.0 (10.05)			127 5.8 (7.95)		
Week 26 chg		121 -25.4 (13.63)	-24.33 (0.78)		127 -26.3 (12.87)	-27.34 (0.76)	-3.02 (-5.16, -0.87) 0.006 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8724
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.443.4.1: Total, Region, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 28.6 (7.70)		22	22 28.9 (7.99)		
Week 26		16 8.1 (7.93)			18 5.1 (6.24)		
Week 26 chg		16 -20.3 (9.09)	-20.12 (1.64)		18 -23.3 (11.28)	-23.14 (1.57)	-3.01 (-7.71, 1.69) 0.200 [-0.29 (-0.97, 0.38)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8724
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.443.4.1: Total, Region, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 34.6 (13.98)		116	116 32.7 (12.01)		
Week 26		105 9.2 (10.36)			109 5.9 (8.22)		
Week 26 chg		105 -26.2 (14.07)	-25.00 (0.86)		109 -26.8 (13.09)	-27.97 (0.85)	-2.97 (-5.37, -0.58) 0.015 [-0.22 (-0.49, 0.05)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8724
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.445.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.39 (0.22)		138 -2.8 (2.87)	-2.85 (0.22)	-0.46 (-1.07, 0.15) 0.140 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.20 (0.22)		137 -3.8 (2.99)	-3.79 (0.22)	-0.58 (-1.20, 0.03) 0.062 [-0.19 (-0.42, 0.05)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.13 (0.22)		134 -4.1 (2.81)	-4.06 (0.22)	-0.93 (-1.54, -0.31) 0.003 [-0.30 (-0.54, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.47 (0.22)		130 -4.4 (2.91)	-4.33 (0.22)	-0.85 (-1.47, -0.24) 0.007 [-0.27 (-0.52, -0.03)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.62 (0.22)		130 -4.5 (2.93)	-4.44 (0.22)	-0.82 (-1.43, -0.20) 0.009 [-0.26 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.70 (0.22)		128 -4.6 (2.96)	-4.53 (0.22)	-0.83 (-1.45, -0.21) 0.008 [-0.26 (-0.51, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.16.445.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	2.8 (2.94)		127	2.3 (2.60)		
Week 14 chg	126	-4.0 (3.48)	-3.86 (0.22)	127	-4.4 (3.07)	-4.31 (0.22)	-0.45 (-1.07, 0.17) 0.156 [-0.14 (-0.38, 0.11)]
Week 16	124	2.7 (2.77)		123	1.9 (2.39)		
Week 16 chg	124	-4.1 (3.25)	-3.91 (0.22)	123	-4.7 (2.92)	-4.63 (0.22)	-0.72 (-1.34, -0.10) 0.024 [-0.23 (-0.48, 0.02)]
Week 18	116	2.9 (2.83)		115	1.7 (2.27)		
Week 18 chg	116	-3.9 (3.35)	-3.71 (0.23)	115	-4.8 (2.93)	-4.81 (0.23)	-1.10 (-1.73, -0.47) <.001 [-0.35 (-0.61, -0.09)]
Week 20	107	2.6 (2.71)		117	1.8 (2.37)		
Week 20 chg	107	-4.1 (3.17)	-3.95 (0.23)	117	-4.8 (2.97)	-4.78 (0.23)	-0.83 (-1.46, -0.20) 0.010 [-0.27 (-0.53, -0.01)]
Week 22	112	2.5 (2.71)		114	1.5 (2.00)		
Week 22 chg	112	-4.2 (3.34)	-4.07 (0.23)	114	-5.0 (2.85)	-4.94 (0.23)	-0.87 (-1.51, -0.24) 0.007 [-0.28 (-0.54, -0.02)]
Week 24	112	2.3 (2.55)		117	1.5 (2.05)		
Week 24 chg	112	-4.4 (3.18)	-4.21 (0.23)	117	-5.1 (2.80)	-4.96 (0.23)	-0.76 (-1.39, -0.12) 0.019 [-0.25 (-0.51, 0.01)]
Week 26	118	2.4 (2.70)		125	1.6 (2.07)		
Week 26 chg	118	-4.4 (3.11)	-4.20 (0.23)	125	-5.0 (2.80)	-4.92 (0.22)	-0.72 (-1.35, -0.10) 0.024 [-0.24 (-0.50, 0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

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Table 1.16.445.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Germany								
Baseline	18	18 7.1 (2.27)		22	22 6.7 (2.09)			
Week 2		18 4.4 (2.95)			22 3.4 (2.02)			
Week 2 chg		18 -2.7 (3.77)	-2.46 (0.62)		22 -3.3 (2.06)	-3.33 (0.56)	-0.87 (-2.56, 0.82) [-0.30 (-0.92, 0.33)]	0.306
Week 4		17 3.2 (2.88)			22 2.8 (2.64)			
Week 4 chg		17 -3.9 (3.51)	-3.53 (0.63)		22 -3.9 (2.51)	-3.94 (0.56)	-0.42 (-2.12, 1.28) [-0.14 (-0.77, 0.49)]	0.626
Week 6		17 3.6 (3.12)			22 2.4 (2.60)			
Week 6 chg		17 -3.5 (3.57)	-3.14 (0.63)		22 -4.3 (2.41)	-4.35 (0.56)	-1.21 (-2.91, 0.49) [-0.41 (-1.05, 0.23)]	0.159
Week 8		17 3.8 (3.20)			20 1.7 (2.19)			
Week 8 chg		17 -3.3 (3.69)	-2.91 (0.63)		20 -5.0 (2.43)	-4.95 (0.57)	-2.04 (-3.75, -0.33) [-0.66 (-1.33, 0.00)]	0.021
Week 10		17 3.0 (2.81)			20 1.3 (2.17)			
Week 10 chg		17 -4.1 (3.73)	-3.57 (0.63)		20 -5.3 (2.99)	-5.34 (0.57)	-1.77 (-3.48, -0.06) [-0.53 (-1.19, 0.13)]	0.043
Week 12		16 3.3 (3.11)			19 1.5 (2.20)			
Week 12 chg		16 -3.7 (3.79)	-3.23 (0.64)		19 -5.2 (2.93)	-5.12 (0.58)	-1.90 (-3.62, -0.17) [-0.57 (-1.24, 0.11)]	0.032
Week 14		17 3.6 (3.50)			19 1.3 (1.49)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

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Table 1.16.445.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	17	-3.5 (4.17)	-3.03 (0.63)	19	-5.2 (2.35)	-5.26 (0.58)	-2.23 (-3.95, -0.51) 0.012 [-0.67 (-1.34, 0.00)]
Week 16	17	3.2 (3.13)		19	1.4 (1.88)		
Week 16 chg	17	-3.9 (3.52)	-3.47 (0.63)	19	-5.1 (2.35)	-5.10 (0.58)	-1.63 (-3.34, 0.09) 0.063 [-0.55 (-1.22, 0.12)]
Week 18	17	3.3 (3.08)		19	1.4 (2.35)		
Week 18 chg	17	-3.8 (3.39)	-3.37 (0.63)	19	-5.2 (2.66)	-5.17 (0.58)	-1.81 (-3.52, -0.09) 0.040 [-0.60 (-1.27, 0.07)]
Week 20	15	3.6 (3.42)		18	0.9 (1.18)		
Week 20 chg	15	-3.4 (4.09)	-2.87 (0.64)	18	-5.5 (1.76)	-5.35 (0.58)	-2.48 (-4.22, -0.74) 0.006 [-0.82 (-1.53, -0.10)]
Week 22	15	2.7 (2.76)		18	1.1 (1.26)		
Week 22 chg	15	-4.1 (3.53)	-3.53 (0.64)	18	-5.3 (2.19)	-5.15 (0.58)	-1.63 (-3.37, 0.11) 0.066 [-0.57 (-1.26, 0.13)]
Week 24	15	2.6 (2.80)		18	1.0 (1.37)		
Week 24 chg	15	-4.2 (3.47)	-3.67 (0.64)	18	-5.4 (2.02)	-5.22 (0.58)	-1.56 (-3.30, 0.18) 0.079 [-0.56 (-1.26, 0.14)]
Week 26	15	2.8 (3.03)		18	1.3 (1.61)		
Week 26 chg	15	-4.0 (3.37)	-3.48 (0.64)	18	-5.1 (2.14)	-4.91 (0.58)	-1.44 (-3.18, 0.30) 0.104 [-0.52 (-1.22, 0.18)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.16.445.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Rest of World										
Baseline	119	119	6.7 (2.20)		116	116	6.7 (2.42)			
Week 2		119	4.3 (2.73)			116	3.9 (2.83)			
Week 2 chg		119	-2.4 (2.87)	-2.37 (0.24)		116	-2.7 (2.99)	-2.77 (0.24)	-0.39 (-1.06, 0.27) [-0.13 (-0.39, 0.12)]	0.243
Week 4		117	3.5 (2.74)			115	2.9 (2.70)			
Week 4 chg		117	-3.2 (3.27)	-3.15 (0.24)		115	-3.7 (3.08)	-3.76 (0.24)	-0.61 (-1.27, 0.06) [-0.19 (-0.45, 0.07)]	0.073
Week 6		115	3.5 (2.86)			112	2.6 (2.58)			
Week 6 chg		115	-3.2 (3.28)	-3.12 (0.24)		112	-4.1 (2.89)	-4.00 (0.24)	-0.88 (-1.55, -0.21) [-0.29 (-0.55, -0.02)]	0.010
Week 8		116	3.1 (2.61)			110	2.4 (2.51)			
Week 8 chg		116	-3.6 (3.25)	-3.55 (0.24)		110	-4.3 (2.99)	-4.22 (0.24)	-0.67 (-1.33, 0.00) [-0.21 (-0.47, 0.05)]	0.051
Week 10		114	3.0 (2.79)			110	2.3 (2.60)			
Week 10 chg		114	-3.7 (3.34)	-3.61 (0.24)		110	-4.3 (2.90)	-4.28 (0.24)	-0.67 (-1.34, 0.00) [-0.21 (-0.48, 0.05)]	0.051
Week 12		112	2.9 (2.62)			109	2.2 (2.52)			
Week 12 chg		112	-3.9 (3.32)	-3.76 (0.24)		109	-4.5 (2.97)	-4.43 (0.24)	-0.67 (-1.34, 0.00) [-0.21 (-0.48, 0.05)]	0.051
Week 14		109	2.6 (2.85)			108	2.5 (2.71)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.16.445.4.1: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	109	109	-4.1 (3.37)	-3.98	(0.24)	108	108	-4.2 (3.16)	-4.15	(0.24)	-0.17 (-0.84, 0.50) [-0.05 (-0.32, 0.21)]	0.623
Week 16	107	107	2.6 (2.72)			104	104	2.0 (2.47)				
Week 16 chg	107	107	-4.1 (3.23)	-3.97	(0.24)	104	104	-4.6 (3.02)	-4.54	(0.24)	-0.57 (-1.25, 0.11) [-0.18 (-0.45, 0.09)]	0.098
Week 18	99	99	2.8 (2.80)			96	96	1.7 (2.26)				
Week 18 chg	99	99	-3.9 (3.36)	-3.76	(0.25)	96	96	-4.7 (2.99)	-4.74	(0.25)	-0.98 (-1.67, -0.29) [-0.31 (-0.59, -0.03)]	0.005
Week 20	92	92	2.4 (2.57)			99	99	1.9 (2.50)				
Week 20 chg	92	92	-4.2 (3.00)	-4.12	(0.25)	99	99	-4.7 (3.13)	-4.68	(0.25)	-0.56 (-1.25, 0.13) [-0.18 (-0.47, 0.10)]	0.112
Week 22	97	97	2.4 (2.71)			96	96	1.6 (2.11)				
Week 22 chg	97	97	-4.3 (3.33)	-4.14	(0.25)	96	96	-4.9 (2.96)	-4.90	(0.25)	-0.76 (-1.45, -0.07) [-0.24 (-0.52, 0.04)]	0.031
Week 24	97	97	2.2 (2.52)			99	99	1.6 (2.14)				
Week 24 chg	97	97	-4.5 (3.15)	-4.28	(0.25)	99	99	-5.0 (2.93)	-4.91	(0.25)	-0.63 (-1.31, 0.06) [-0.21 (-0.49, 0.07)]	0.073
Week 26	103	103	2.4 (2.66)			107	107	1.7 (2.14)				
Week 26 chg	103	103	-4.5 (3.08)	-4.29	(0.24)	107	107	-4.9 (2.91)	-4.90	(0.24)	-0.61 (-1.29, 0.07) [-0.20 (-0.47, 0.07)]	0.078

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3568
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

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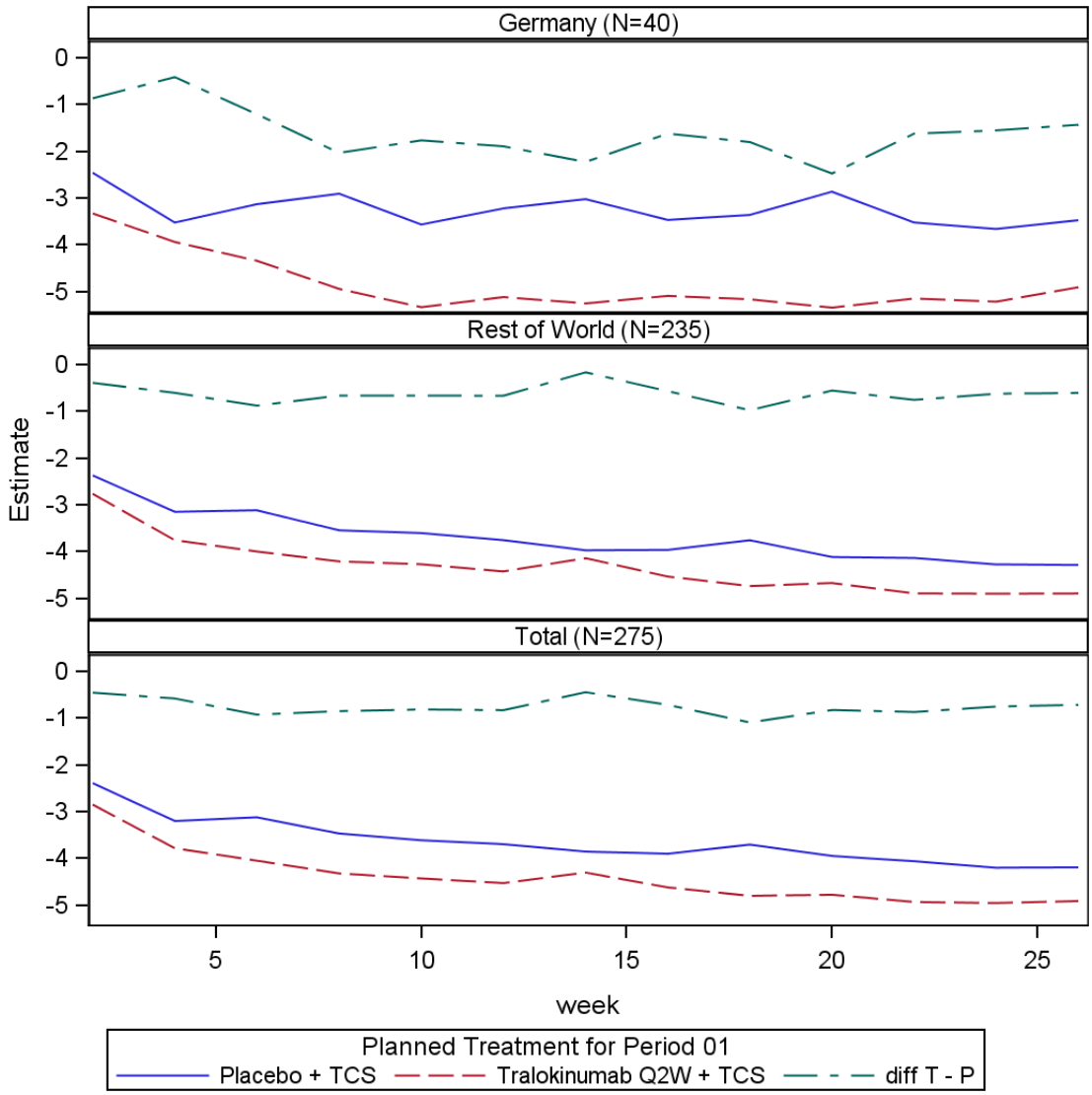
Figure 1.16.445.4.2: Total, Region, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.16.446.4.1: Total, Region, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.89 (0.84)		123 -25.9 (12.78)	-26.75 (0.84)	-3.86 (-6.21, -1.51) 0.001 [-0.28 (-0.53, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6685
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.446.4.1: Total, Region, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	18 28.6 (7.70)		22	22 28.9 (7.99)		
Week 16		17 11.2 (14.59)			19 4.4 (2.89)		
Week 16 chg		17 -17.9 (13.49)	-17.54 (2.38)		19 -23.6 (8.55)	-24.02 (2.27)	-6.47 (-13.3, 0.31) 0.061 [-0.58 (-1.25, 0.09)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6685
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.446.4.1: Total, Region, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World							
Baseline	119	119 34.6 (13.98)		116	116 32.7 (12.01)		
Week 16		107 10.4 (10.92)			104 6.8 (8.16)		
Week 16 chg		107 -24.7 (15.00)	-23.76 (0.90)		104 -26.3 (13.40)	-27.21 (0.91)	-3.45 (-5.99, -0.92) 0.008 [-0.24 (-0.51, 0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6685
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.463.4.1: Total, Region, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Physical component summary												
Total												
Baseline	137	134	44.5 (8.19)			138	134	44.5 (7.83)				
Week 8		129	50.3 (7.06)				129	51.7 (7.07)				
Week 8 chg		129	5.6 (7.75)	5.69	(0.56)		129	7.4 (7.27)	7.16	(0.56)	1.47 (-0.08, 3.03) [0.20 (-0.05, 0.44)]	0.063
Week 16		119	50.9 (7.78)				113	52.9 (6.85)				
Week 16 chg		119	6.8 (8.15)	6.49	(0.57)		113	8.0 (7.67)	7.87	(0.58)	1.39 (-0.22, 2.99) [0.17 (-0.08, 0.43)]	0.090

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8215
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.463.4.1: Total, Region, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 42.4 (7.95)		22	22 42.9 (7.28)		
Week 8		17 49.5 (6.60)			21 50.9 (7.54)		
Week 8 chg		17 7.1 (9.72)	6.66 (1.83)		21 8.1 (8.57)	7.98 (1.63)	1.32 (-3.63, 6.27) 0.594 [0.14 (-0.50, 0.79)]
Week 16		16 48.9 (9.14)			19 53.3 (6.54)		
Week 16 chg		16 6.7 (9.84)	6.09 (1.86)		19 9.2 (8.15)	8.62 (1.67)	2.54 (-2.52, 7.60) 0.318 [0.28 (-0.39, 0.95)]

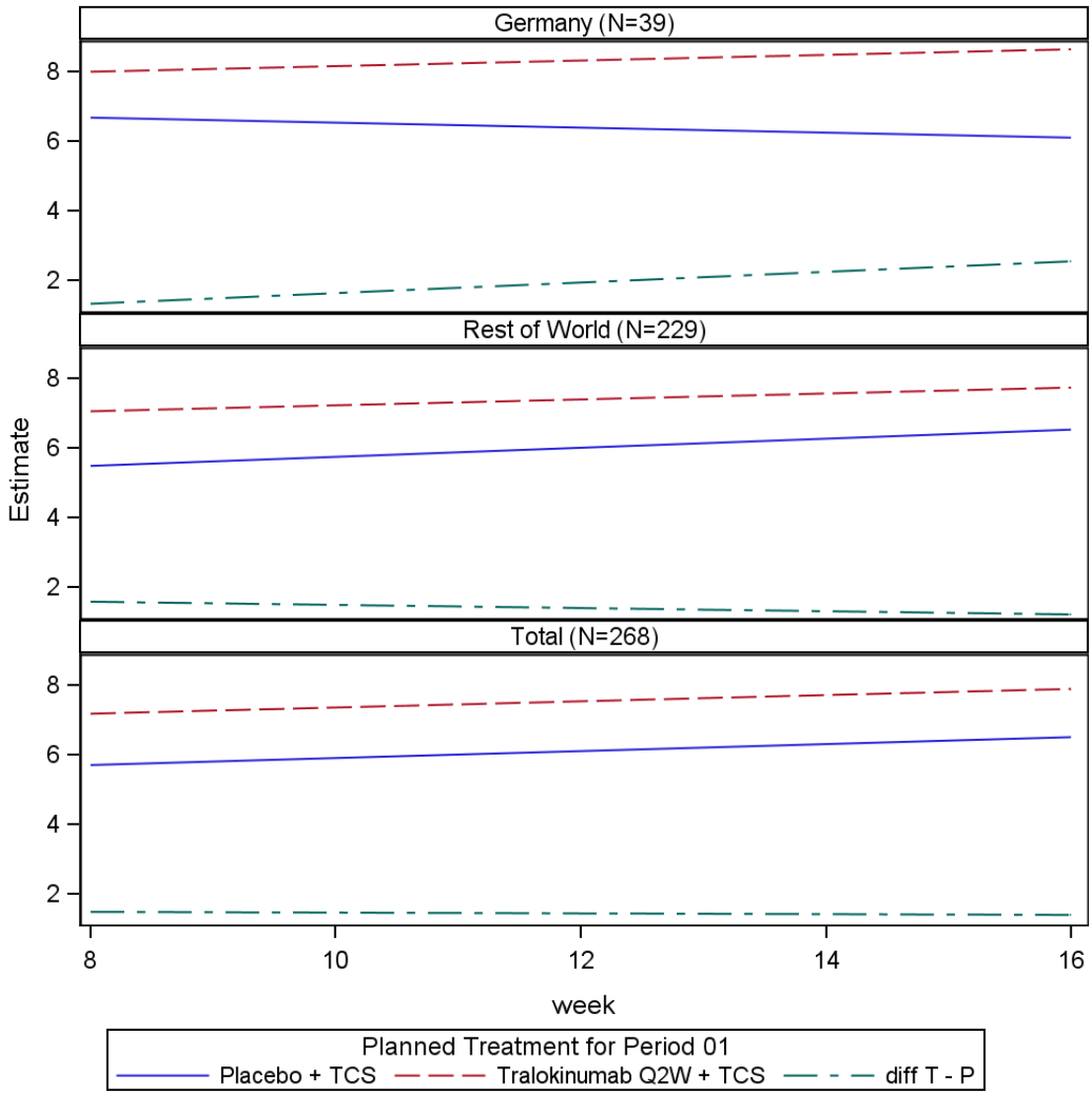
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8215
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.463.4.1: Total, Region, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World									
Baseline	119	117	44.8 (8.22)		116	112	44.8 (7.93)		
Week 8		112	50.4 (7.15)			108	51.9 (7.00)		
Week 8 chg		112	5.3 (7.43)	5.47 (0.58)		108	7.2 (7.03)	7.04 (0.60)	1.57 (-0.07, 3.21) 0.061 [0.22 (-0.05, 0.48)]
Week 16		103	51.2 (7.55)			94	52.8 (6.94)		
Week 16 chg		103	6.8 (7.92)	6.51 (0.60)		94	7.7 (7.59)	7.72 (0.62)	1.21 (-0.49, 2.90) 0.163 [0.16 (-0.12, 0.44)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8215
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.463.4.2: Total, Region, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, 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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.464.4.1: Total, Region, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary							
Total							
Baseline	137	134 44.9 (11.42)		138	134 46.3 (9.74)		
Week 8		129 49.6 (10.25)			129 49.7 (9.51)		
Week 8 chg		129 4.4 (7.37)	4.13 (0.64)		129 3.7 (8.69)	3.69 (0.63)	-0.44 (-2.21, 1.33) 0.625 [-0.05 (-0.30, 0.19)]
Week 16		119 49.5 (10.11)			113 49.9 (9.68)		
Week 16 chg		119 4.4 (8.65)	4.08 (0.65)		113 3.4 (8.59)	3.59 (0.66)	-0.50 (-2.32, 1.33) 0.594 [-0.06 (-0.32, 0.20)]
Week 26		110 50.4 (9.75)			112 51.4 (7.72)		
Week 26 chg		110 5.5 (8.68)	4.92 (0.67)		112 4.6 (8.26)	4.50 (0.66)	-0.42 (-2.27, 1.44) 0.660 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9803
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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.

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Table 1.16.464.4.1: Total, Region, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 47.0 (12.79)		22	22 47.2 (9.85)		
Week 8		17 51.9 (8.63)			21 50.7 (10.79)		
Week 8 chg		17 4.8 (8.09)	4.81 (1.78)		21 4.1 (10.23)	3.75 (1.58)	-1.06 (-5.87, 3.75) 0.659 [-0.11 (-0.75, 0.53)]
Week 16		16 53.0 (7.10)			19 49.8 (9.28)		
Week 16 chg		16 4.7 (6.44)	4.55 (1.81)		19 3.1 (9.29)	2.98 (1.63)	-1.57 (-6.48, 3.35) 0.525 [-0.19 (-0.86, 0.47)]
Week 26		13 53.1 (4.86)			18 51.9 (7.80)		
Week 26 chg		13 5.6 (10.54)	4.89 (1.89)		18 4.9 (8.57)	3.70 (1.65)	-1.20 (-6.24, 3.85) 0.637 [-0.13 (-0.84, 0.59)]

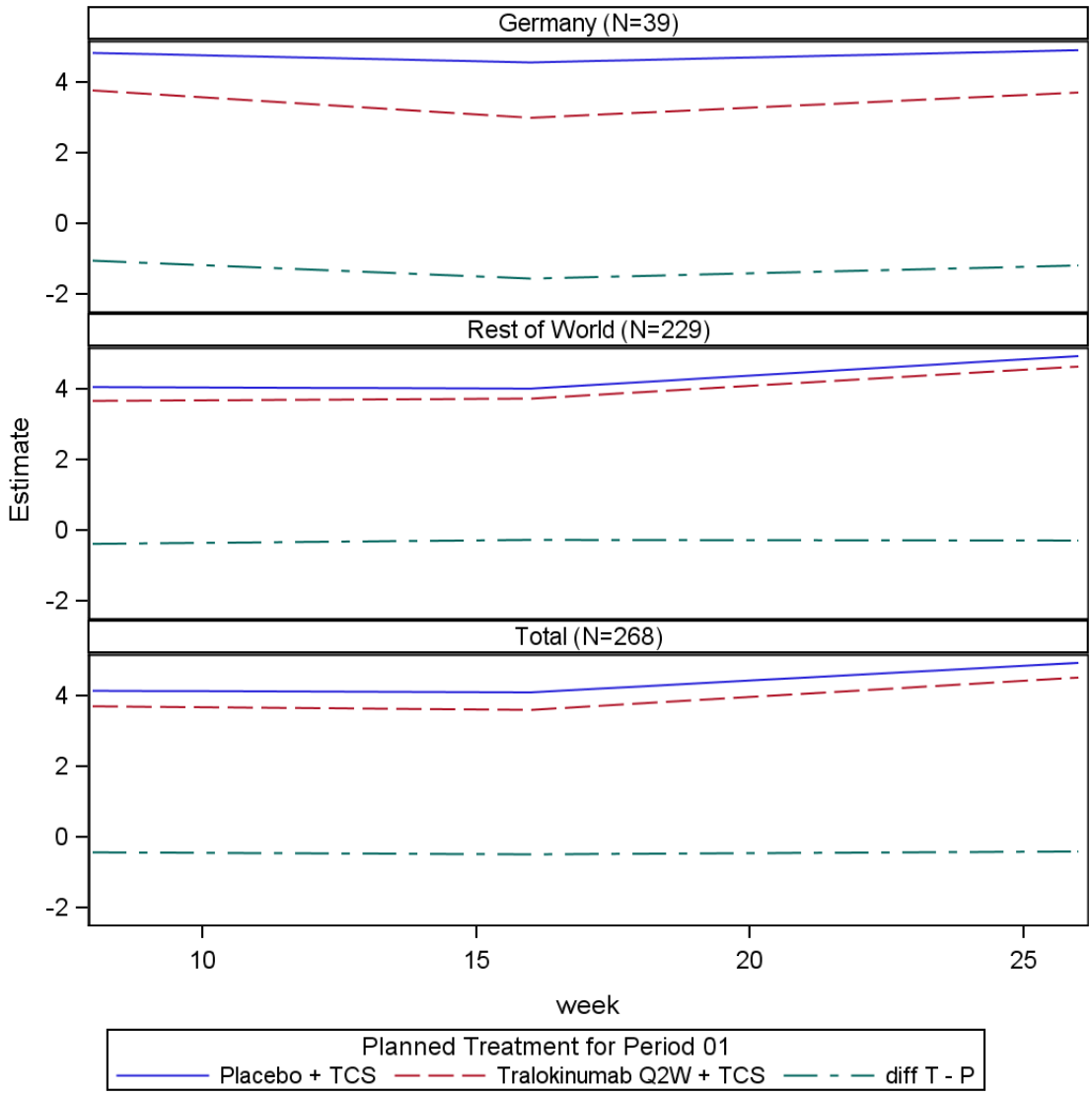
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9803
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.464.4.1: Total, Region, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World									
Baseline	119	117	44.6 (11.24)		116	112	46.1 (9.76)		
Week 8		112	49.2 (10.46)			108	49.5 (9.29)		
Week 8 chg		112	4.3 (7.29)	4.04 (0.69)		108	3.6 (8.41)	3.65 (0.70)	-0.39 (-2.32, 1.54) 0.690 [-0.05 (-0.31, 0.21)]
Week 16		103	48.9 (10.42)			94	49.9 (9.81)		
Week 16 chg		103	4.3 (8.97)	4.00 (0.71)		94	3.5 (8.50)	3.71 (0.73)	-0.28 (-2.29, 1.72) 0.783 [-0.03 (-0.31, 0.25)]
Week 26		97	50.1 (10.19)			94	51.3 (7.74)		
Week 26 chg		97	5.4 (8.46)	4.92 (0.72)		94	4.5 (8.25)	4.62 (0.73)	-0.30 (-2.33, 1.73) 0.773 [-0.04 (-0.32, 0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9803
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.464.4.2: Total, Region, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.465.4.1: Total, Region, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary									
Total									
Baseline	137	134	44.5 (8.19)		138	134	44.5 (7.83)		
Week 8		129	50.3 (7.06)			129	51.7 (7.07)		
Week 8 chg		129	5.6 (7.75)	5.70 (0.56)		129	7.4 (7.27)	7.18 (0.56)	1.48 (-0.09, 3.04) 0.064 [0.20 (-0.05, 0.44)]
Week 16		119	50.9 (7.78)			113	52.9 (6.85)		
Week 16 chg		119	6.8 (8.15)	6.57 (0.57)		113	8.0 (7.67)	7.95 (0.58)	1.37 (-0.23, 2.98) 0.093 [0.17 (-0.08, 0.43)]
Week 26		110	50.7 (7.62)			112	52.9 (7.40)		
Week 26 chg		110	6.9 (8.19)	6.11 (0.59)		112	8.2 (7.71)	8.22 (0.58)	2.11 (0.48, 3.74) 0.011 [0.27 (0.00, 0.53)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9135
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.465.4.1: Total, Region, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 42.4 (7.95)		22	22 42.9 (7.28)		
Week 8		17 49.5 (6.60)			21 50.9 (7.54)		
Week 8 chg		17 7.1 (9.72)	6.65 (1.77)		21 8.1 (8.57)	7.99 (1.57)	1.34 (-3.44, 6.11) 0.575 [0.15 (-0.49, 0.79)]
Week 16		16 48.9 (9.14)			19 53.3 (6.54)		
Week 16 chg		16 6.7 (9.84)	6.09 (1.80)		19 9.2 (8.15)	8.70 (1.62)	2.61 (-2.28, 7.50) 0.288 [0.29 (-0.38, 0.96)]
Week 26		13 49.4 (7.90)			18 54.4 (4.65)		
Week 26 chg		13 8.6 (10.38)	5.91 (1.89)		18 10.2 (7.28)	9.65 (1.64)	3.75 (-1.32, 8.81) 0.144 [0.43 (-0.29, 1.15)]

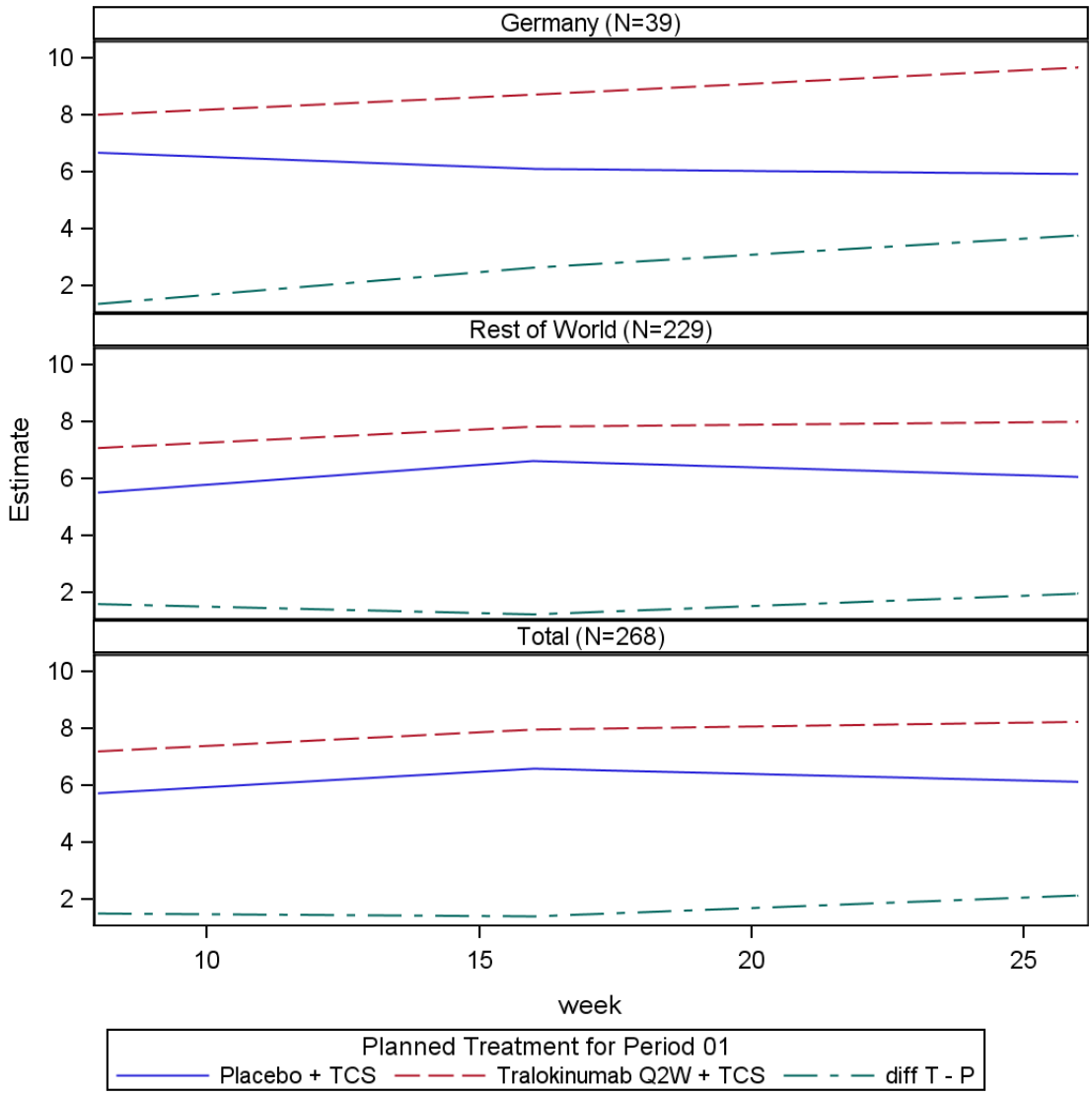
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9135
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.465.4.1: Total, Region, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World									
Baseline	119	117	44.8 (8.22)		116	112	44.8 (7.93)		
Week 8		112	50.4 (7.15)			108	51.9 (7.00)		
Week 8 chg		112	5.3 (7.43)	5.49 (0.59)		108	7.2 (7.03)	7.06 (0.60)	1.57 (-0.10, 3.24) 0.065 [0.22 (-0.05, 0.48)]
Week 16		103	51.2 (7.55)			94	52.8 (6.94)		
Week 16 chg		103	6.8 (7.92)	6.60 (0.61)		94	7.7 (7.59)	7.81 (0.63)	1.21 (-0.51, 2.92) 0.168 [0.16 (-0.12, 0.44)]
Week 26		97	50.9 (7.61)			94	52.6 (7.80)		
Week 26 chg		97	6.6 (7.88)	6.05 (0.62)		94	7.9 (7.77)	7.98 (0.63)	1.94 (0.20, 3.67) 0.028 [0.25 (-0.04, 0.53)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9135
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.465.4.2: Total, Region, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.466.4.1: Total, Region, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 8		129	49.6 (10.25)				129	49.7 (9.51)			
Week 8 chg		129	4.4 (7.37)	4.14	(0.65)		129	3.7 (8.69)	3.66	(0.65)	-0.47 (-2.28, 1.34) 0.607 [-0.06 (-0.30, 0.19)]
Week 16		119	49.5 (10.11)				113	49.9 (9.68)			
Week 16 chg		119	4.4 (8.65)	4.09	(0.67)		113	3.4 (8.59)	3.63	(0.68)	-0.46 (-2.34, 1.42) 0.629 [-0.05 (-0.31, 0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8794
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.466.4.1: Total, Region, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 47.0 (12.79)		22	22 47.2 (9.85)		
Week 8		17 51.9 (8.63)			21 50.7 (10.79)		
Week 8 chg		17 4.8 (8.09)	4.84 (1.79)		21 4.1 (10.23)	3.86 (1.59)	-0.98 (-5.82, 3.86) 0.685 [-0.10 (-0.74, 0.54)]
Week 16		16 53.0 (7.10)			19 49.8 (9.28)		
Week 16 chg		16 4.7 (6.44)	4.50 (1.82)		19 3.1 (9.29)	2.99 (1.62)	-1.51 (-6.43, 3.42) 0.541 [-0.19 (-0.85, 0.48)]

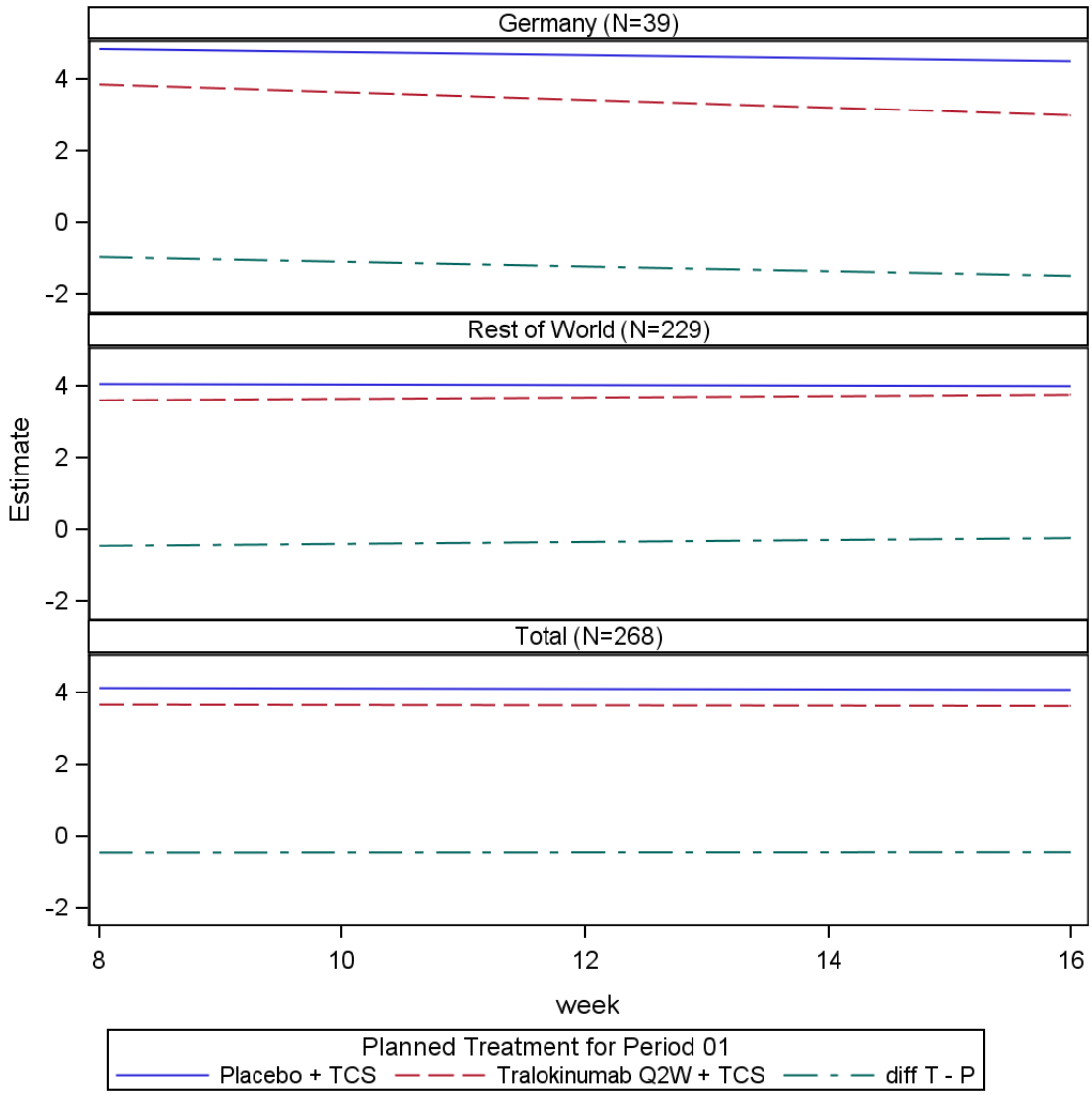
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8794
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.466.4.1: Total, Region, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	117	44.6 (11.24)			116	112	46.1 (9.76)			
Week 8		112	49.2 (10.46)				108	49.5 (9.29)			
Week 8 chg		112	4.3 (7.29)	4.06	(0.70)		108	3.6 (8.41)	3.60	(0.72)	-0.45 (-2.44, 1.53) 0.653 [-0.06 (-0.32, 0.21)]
Week 16		103	48.9 (10.42)				94	49.9 (9.81)			
Week 16 chg		103	4.3 (8.97)	4.00	(0.73)		94	3.5 (8.50)	3.76	(0.76)	-0.24 (-2.30, 1.83) 0.820 [-0.03 (-0.31, 0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8794
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.466.4.2: Total, Region, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, 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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.16.469.4.1: Total, Region, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 26		115	50.7 (9.70)				118	51.1 (7.88)			
Week 26 chg		113	5.6 (8.87)	5.14	(0.66)		114	4.4 (8.31)	4.80	(0.66)	-0.34 (-2.18, 1.50) 0.715 [-0.04 (-0.30, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6892
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.469.4.1: Total, Region, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 47.0 (12.79)		22	22 47.2 (9.85)		
Week 26		15 53.8 (5.10)			18 51.9 (7.80)		
Week 26 chg		14 5.2 (10.26)	5.74 (1.58)		18 4.9 (8.57)	4.43 (1.42)	-1.32 (-5.69, 3.06) 0.543 [-0.14 (-0.84, 0.56)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6892
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.469.4.1: Total, Region, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	117	44.6 (11.24)			116	112	46.1 (9.76)			
Week 26		100	50.2 (10.15)				100	51.0 (7.92)			
Week 26 chg		99	5.7 (8.71)	5.10	(0.72)		96	4.3 (8.31)	4.83	(0.73)	-0.27 (-2.31, 1.77) 0.795 [-0.03 (-0.31, 0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6892
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.470.4.1: Total, Region, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary							
Total							
Baseline	137	134 44.5 (8.19)		138	134 44.5 (7.83)		
Week 26		115 50.9 (7.60)			118 52.8 (7.38)		
Week 26 chg		113 6.8 (8.15)	6.63 (0.62)		114 8.4 (7.77)	8.47 (0.62)	1.84 (0.11, 3.56) 0.037 [0.23 (-0.03, 0.49)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4497
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.470.4.1: Total, Region, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany											
Baseline	18	17	42.4 (7.95)			22	22	42.9 (7.28)			
Week 26		15	49.7 (7.94)				18	54.4 (4.65)			
Week 26 chg		14	8.0 (10.19)	6.41	(1.66)		18	10.2 (7.28)	11.71	(1.47)	5.30 (0.69, 9.92) 0.026 [0.61 (-0.10, 1.33)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4497
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.470.4.1: Total, Region, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	117	44.8 (8.22)			116	112	44.8 (7.93)			
Week 26		100	51.1 (7.58)				100	52.5 (7.75)			
Week 26 chg		99	6.6 (7.87)	6.52	(0.66)		96	8.0 (7.84)	8.03	(0.67)	1.51 (-0.36, 3.38) 0.114 [0.19 (-0.09, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4497
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.471.4.1: Total, Region, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 16		121	49.5 (10.08)				117	50.1 (9.57)			
Week 16 chg		119	4.4 (8.65)	4.12	(0.70)		113	3.4 (8.59)	3.70	(0.72)	-0.42 (-2.41, 1.56) 0.675 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6458
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.471.4.1: Total, Region, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 47.0 (12.79)		22	22 47.2 (9.85)		
Week 16		17 53.1 (6.89)			19 49.8 (9.28)		
Week 16 chg		16 4.7 (6.44)	5.05 (1.61)		19 3.1 (9.29)	2.91 (1.48)	-2.14 (-6.64, 2.36) 0.339 [-0.26 (-0.93, 0.40)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6458
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.471.4.1: Total, Region, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	117	44.6 (11.24)			116	112	46.1 (9.76)			
Week 16		104	48.9 (10.41)				98	50.1 (9.67)			
Week 16 chg		103	4.3 (8.97)	3.99	(0.78)		94	3.5 (8.50)	3.84	(0.82)	-0.15 (-2.38, 2.09) 0.898 [-0.02 (-0.30, 0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6458
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.472.4.1: Total, Region, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary									
Total									
Baseline	137	134	44.5 (8.19)		138	134	44.5 (7.83)		
Week 16		121	51.0 (7.75)			117	52.8 (6.79)		
Week 16 chg		119	6.8 (8.15)	6.60 (0.60)		113	8.0 (7.67)	8.20 (0.61)	1.60 (-0.09, 3.28) 0.063 [0.20 (-0.06, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6157
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.472.4.1: Total, Region, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Germany							
Baseline	18	17 42.4 (7.95)		22	22 42.9 (7.28)		
Week 16		17 49.4 (9.05)			19 53.3 (6.54)		
Week 16 chg		16 6.7 (9.84)	5.91 (1.93)		19 9.2 (8.15)	10.02 (1.78)	4.11 (-1.31, 9.53) 0.132 [0.46 (-0.21, 1.13)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6157
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.472.4.1: Total, Region, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Rest of World											
Baseline	119	117	44.8 (8.22)			116	112	44.8 (7.93)			
Week 16		104	51.3 (7.53)				98	52.7 (6.87)			
Week 16 chg		103	6.8 (7.92)	6.65	(0.62)		94	7.7 (7.59)	7.91	(0.65)	1.25 (-0.53, 3.04) 0.167 [0.16 (-0.12, 0.44)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6157
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.16.701.4.1: Total, Any TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Germany						18	8.4		22	9.9	
Rest of World						119	57.0		116	55.5	
Any system organ class											
Any preferred term											
Total	0.7484	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385
Germany		0.8029	1.03 (0.84, 1.26)	1.30 (0.17, 10.1)	2.4 (-17, 21.6)	16	(88.9)	46	20	(90.9)	62
Rest of World		0.6787	0.97 (0.84, 1.12)	0.88 (0.48, 1.60)	-2.3 (-13, 8.59)	92	(77.3)	377	87	(75.0)	323

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 1.16.702.4.1: Total, Any drug-related TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Germany						18	8.4		22	9.9	
Rest of World						119	57.0		116	55.5	
Any system organ class											
Any preferred term											
Total	0.2308	0.2852	1.19 (0.86, 1.65)	1.32 (0.80, 2.17)	6.1 (-5.0, 17.3)	43	(31.4)	94	52	(37.7)	105
Germany		0.4402	0.79 (0.44, 1.42)	0.59 (0.16, 2.19)	-12 (-42, 17.7)	10	(55.6)	16	10	(45.5)	19
Rest of World		0.1692	1.30 (0.89, 1.89)	1.48 (0.85, 2.57)	8.4 (-3.5, 20.2)	33	(27.7)	78	42	(36.2)	86

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 1.16.703.4.1: Total, Any TEAE causing permanent discontinuation, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Germany						18 8.4		22 9.9	
Rest of World						119 57.0		116 55.5	
Any system organ class									
Any preferred term									
Total	Not est.	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3 (2.2)	4	1 (0.7)	1
Rest of World		0.3336	0.34 (0.03, 3.39)	0.34 (0.04, 3.31)	-1.6 (-4.9, 1.65)	3 (2.5)	4	1 (0.9)	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. TEAE: Treatment emergent adverse events

Table 1.16.704.4.1: Total, Any mild TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Germany						18	8.4		22	9.9	
Rest of World						119	57.0		116	55.5	
Any system organ class											
Any preferred term											
Total	0.7640	0.9615	1.00 (0.87, 1.16)	1.01 (0.60, 1.71)	0.3 (-10, 10.9)	98	(71.5)	293	99	(71.7)	300
Germany		0.7525	1.04 (0.80, 1.35)	1.34 (0.23, 7.79)	3.7 (-19, 25.9)	15	(83.3)	36	19	(86.4)	53
Rest of World		0.8988	0.99 (0.83, 1.17)	0.96 (0.55, 1.68)	-0.8 (-13, 11.0)	83	(69.7)	257	80	(69.0)	247

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 1.16.705.4.1: Total, Any moderate TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Germany						18	8.4		22	9.9	
Rest of World						119	57.0		116	55.5	
Any system organ class											
Any preferred term											
Total	0.5891	0.0876	0.75 (0.53, 1.05)	0.65 (0.39, 1.07)	-9.8 (-21, 1.39)	53	(38.7)	121	40	(29.0)	82
Germany		0.2031	0.55 (0.22, 1.40)	0.43 (0.11, 1.67)	-18 (-47, 10.4)	7	(38.9)	10	5	(22.7)	8
Rest of World		0.1732	0.78 (0.55, 1.12)	0.69 (0.40, 1.18)	-8.5 (-21, 3.63)	46	(38.7)	111	35	(30.2)	74

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 1.16.706.4.1: Total, Any severe TEAE, LP0162-1346, 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 + TCSE n (%)	Placebo + TCSE E	Tralokinumab Q2W + TCSE n (%)	Tralokinumab Q2W + TCSE E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Germany						18 8.4		22 9.9	
Rest of World						119 57.0		116 55.5	
Any system organ class									
Any preferred term									
Total	0.1029	0.1235	0.37 (0.10, 1.38)	0.36 (0.09, 1.39)	-3.7 (-8.3, 0.97)	8 (5.8)	9	3 (2.2)	3
Germany		0.3367			4.9 (-4.1, 13.9)	0 (0.0)	0	1 (4.5)	1
Rest of World		0.0590	0.26 (0.06, 1.18)	0.24 (0.05, 1.17)	-5.0 (-10, 0.09)	8 (6.7)	9	2 (1.7)	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. TEAE: Treatment emergent adverse events

Table 1.16.707.4.1: Total, Death, LP0162-1346, Adverse events subgroup tests by PT

SOC / Preferred term / Subgroup	ChiSq / p-value	CMH RR / 95%CI	CMH OR / 95%CI	CMH RD / 95%CI	Placebo + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Germany					18	8.4		22	9.9	
Rest of World					119	57.0		116	55.5	

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.

Table 1.16.708.4.1: Total, Any TE SAE, LP0162-1346, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Analysis set							
N, Exposure(years)							
Total						137 65.4	138 65.4
Germany						18 8.4	22 9.9
Rest of World						119 57.0	116 55.5
Any system organ class							
Any preferred term							
Total	Not est.	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5 (3.6) 9	1 (0.7) 1
Rest of World		0.1081	0.21 (0.03, 1.73)	0.20 (0.02, 1.74)	-3.3 (-7.3, 0.66)	5 (4.2) 9	1 (0.9) 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. TE SAE: Treatment emergent serious adverse events

Table 1.16.709.4.1: Total, Any drug-related TE SAE, LP0162-1346, 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 + TCS n (%)	E	Tralokinumab Q2W + TCS n (%)	E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Germany						18 8.4		22 9.9	
Rest of World						119 57.0		116 55.5	
Any system organ class									
Any preferred term									
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)	3	0 (0.0)	0
Rest of World		0.1666	0.00 (not est.)	0.00 (not est.)	-1.7 (-4.0, 0.64)	2 (1.7)	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 1.16.710.4.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Germany						18 8.4		22 9.9	
Rest of World						119 57.0		116 55.5	
Any system organ class									
Any preferred term									
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)	3	0 (0.0)	0
Rest of World		0.1666	0.00 (not est.)	0.00 (not est.)	-1.7 (-4.0, 0.64)	2 (1.7)	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 1.16.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Germany						18	8.4		22	9.9	
Rest of World						119	57.0		116	55.5	
Any system organ class											
Any preferred term											
Total	0.7484	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385
Germany		0.8029	1.03 (0.84, 1.26)	1.30 (0.17, 10.1)	2.4 (-17, 21.6)	16	(88.9)	46	20	(90.9)	62
Rest of World		0.6787	0.97 (0.84, 1.12)	0.88 (0.48, 1.60)	-2.3 (-13, 8.59)	92	(77.3)	377	87	(75.0)	323
Eye disorders											
Any											
Total	0.0272	0.2842	1.54 (0.69, 3.44)	1.61 (0.67, 3.84)	3.6 (-3.0, 10.1)	9	(6.6)	14	14	(10.1)	17
Gastrointestinal disorders											
Any											
Total	0.7171	0.8349	0.93 (0.48, 1.81)	0.92 (0.44, 1.95)	-0.8 (-8.3, 6.68)	16	(11.7)	23	15	(10.9)	18
General disorders and administration site conditions											
Any											
Total	Not est.	0.1576	1.59 (0.83, 3.03)	1.70 (0.81, 3.57)	5.6 (-2.1, 13.3)	13	(9.5)	16	21	(15.2)	27
Infections and infestations											
Any											
Total	0.6705	0.2533	0.89 (0.72, 1.09)	0.76 (0.47, 1.22)	-6.8 (-18, 4.82)	83	(60.6)	152	74	(53.6)	144

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 1.16.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Upper respiratory tract infection											
Total	Not est.	0.9930	1.00 (0.43, 2.31)	1.00 (0.40, 2.47)	-0.0 (-6.2, 6.12)	10	(7.3)	11	10	(7.2)	12
Viral upper respiratory tract infection											
Total	0.9366	0.7928	1.05 (0.71, 1.57)	1.08 (0.63, 1.84)	1.4 (-9.0, 11.8)	35	(25.5)	46	37	(26.8)	53
Injury, poisoning and procedural complications											
Any											
Total	0.8286	0.5243	1.29 (0.59, 2.84)	1.32 (0.56, 3.08)	2.1 (-4.5, 8.74)	10	(7.3)	12	13	(9.4)	16
Musculoskeletal and connective tissue disorders											
Any											
Total	0.1664	0.4116	1.27 (0.72, 2.24)	1.32 (0.68, 2.57)	3.5 (-4.9, 12.0)	18	(13.1)	28	23	(16.7)	25
Nervous system disorders											
Any											
Total	0.4565	0.6516	1.13 (0.66, 1.94)	1.16 (0.61, 2.20)	2.0 (-6.7, 10.8)	21	(15.3)	31	24	(17.4)	33
Headache											
Total	0.9853	0.1506	1.61 (0.84, 3.09)	1.71 (0.82, 3.57)	5.7 (-2.0, 13.5)	13	(9.5)	18	21	(15.2)	25
Respiratory, thoracic and mediastinal disorders											
Any											
Total	0.1517	0.0335	0.55 (0.31, 0.96)	0.49 (0.25, 0.95)	-9.5 (-18, -.84)	29	(21.2)	38	16	(11.6)	21
Germany		0.1095	0.00 (not est.)	0.00 (not est.)	-11 (-26, 3.30)	2	(11.1)	4	0	(0.0)	0
Rest of World		0.0808	0.61 (0.35, 1.07)	0.55 (0.28, 1.08)	-8.8 (-19, 0.95)	27	(22.7)	34	16	(13.8)	21
Skin and subcutaneous tissue disorders											
Any											

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 1.16.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Total	0.8220	0.1365	0.71 (0.46, 1.12)	0.65 (0.37, 1.15)	-7.5 (-17, 2.33)	36 (26.3)	59	26 (18.8)	44
Dermatitis atopic									
Total	0.0523	0.0498	0.44 (0.19, 1.03)	0.41 (0.16, 1.02)	-6.6 (-13, -.07)	16 (11.7)	26	7 (5.1)	11
Germany		0.3828	2.62 (0.28, 24.1)	2.91 (0.26, 32.3)	8.5 (-9.2, 26.2)	1 (5.6)	1	3 (13.6)	3
Rest of World		0.0105	0.27 (0.09, 0.80)	0.25 (0.08, 0.77)	-9.1 (-16, -2.3)	15 (12.6)	25	4 (3.4)	8
Vascular disorders									
Any									
Total	0.9310	0.0596	0.36 (0.12, 1.10)	0.34 (0.10, 1.09)	-5.2 (-11, 0.16)	11 (8.0)	12	4 (2.9)	6

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 1.16.712.4.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Germany						18	8.4		22	9.9	
Rest of World						119	57.0		116	55.5	
Any system organ class											
Any preferred term											
Total	Not est.	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5	(3.6)	9	1	(0.7)	1
Rest of World		0.1081	0.21 (0.03, 1.73)	0.20 (0.02, 1.74)	-3.3 (-7.3, 0.66)	5	(4.2)	9	1	(0.9)	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. TE SAE: Treatment emergent serious adverse events

Table 1.16.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Germany						18 8.4		22 9.9	
Rest of World						119 57.0		116 55.5	
Any system organ class									
Any preferred term									
Total	Not est.	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3 (2.2)	4	1 (0.7)	1
Rest of World		0.3336	0.34 (0.03, 3.39)	0.34 (0.04, 3.31)	-1.6 (-4.9, 1.65)	3 (2.5)	4	1 (0.9)	1
General disorders and administration site conditions									
Any									
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0 (0.0)	0	1 (0.7)	1
Injection site pain									
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0 (0.0)	0	1 (0.7)	1
Nervous system disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Cerebrovascular accident									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Psychiatric disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	2	0 (0.0)	0
Depressed mood									

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 1.16.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Suicidal ideation									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis atopic									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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. TE SAE: Treatment emergent serious adverse events

Table 1.16.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Germany						18	8.4		22	9.9	
Rest of World						119	57.0		116	55.5	
Any system organ class											
Any preferred term											
Total	0.0783	0.0780	2.14 (0.90, 5.07)	2.28 (0.90, 5.77)	5.8 (-.58, 12.2)	7	(5.1)	9	15	(10.9)	17
Germany		0.5193	0.56 (0.10, 3.31)	0.53 (0.08, 3.58)	-6.9 (-28, 14.0)	3	(16.7)	3	2	(9.1)	2
Rest of World		0.0209	3.32 (1.12, 9.85)	3.59 (1.14, 11.3)	7.8 (1.23, 14.5)	4	(3.4)	6	13	(11.2)	15
Eye disorders											
Any											
Total	0.0855	0.1593	2.23 (0.71, 7.03)	2.30 (0.70, 7.57)	3.6 (-1.4, 8.64)	4	(2.9)	4	9	(6.5)	11
Lacrimation increased											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Exposure keratitis											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Atopic keratoconjunctivitis											
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0	(0.0)	0	1	(0.7)	1
Conjunctivitis allergic											
Total	0.1259	0.5286	1.48 (0.43, 5.11)	1.50 (0.42, 5.40)	1.4 (-3.0, 5.88)	4	(2.9)	4	6	(4.3)	8
Infections and infestations											
Any											
Total	0.4773	0.5286	1.49 (0.43, 5.24)	1.51 (0.42, 5.49)	1.4 (-3.0, 5.84)	4	(2.9)	5	6	(4.3)	6

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

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Table 1.16.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Keratitis viral							
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7) 1	0 (0.0) 0
Herpes ophthalmic							
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7) 1	0 (0.0) 0
Conjunctivitis							
Total	0.2812	0.1591	2.96 (0.61, 14.5)	3.05 (0.60, 15.4)	2.9 (-1.1, 6.81)	2 (1.5) 3	6 (4.3) 6

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 1.16.715.4.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Germany					18	8.4		22	9.9	
Rest of World					119	57.0		116	55.5	

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 1.16.716.4.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Germany						18 8.4		22 9.9	
Rest of World						119 57.0		116 55.5	
Any system organ class									
Any preferred term									
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0 (0.0)	0	1 (0.7)	2
Rest of World		0.3045			0.9 (-.82, 2.57)	0 (0.0)	0	1 (0.9)	2
Infections and infestations									
Any									
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0 (0.0)	0	1 (0.7)	2
Eczema herpeticum									
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0 (0.0)	0	1 (0.7)	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 1.16.717.4.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Germany					18	8.4		22	9.9	
Rest of World					119	57.0		116	55.5	

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 1.16.718.4.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Germany					18	8.4		22	9.9	
Rest of World					119	57.0		116	55.5	

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 1.16.719.4.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Germany					18	8.4		22	9.9	
Rest of World					119	57.0		116	55.5	

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 1.16.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Germany						18 8.4		22 9.9	
Rest of World						119 57.0		116 55.5	
Any system organ class									
Any preferred term									
Total	Not est.	0.0178	0.12 (0.02, 0.99)	0.12 (0.01, 0.96)	-5.1 (-9.3, -.93)	8 (5.8)	12	1 (0.7)	1
Rest of World		0.0200	0.13 (0.02, 1.02)	0.12 (0.01, 0.99)	-5.8 (-11, -1.0)	8 (6.7)	12	1 (0.9)	1
Infections and infestations									
Any									
Total	Not est.	0.0311	0.14 (0.02, 1.15)	0.13 (0.02, 1.12)	-4.4 (-8.3, -.44)	7 (5.1)	11	1 (0.7)	1
Rest of World		0.0347	0.15 (0.02, 1.18)	0.14 (0.02, 1.15)	-5.0 (-9.6, -.47)	7 (5.9)	11	1 (0.9)	1
Staphylococcal skin infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Cellulitis									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Wound infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Oral herpes									
Total	Not est.	0.3067	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.2, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis infected									
Total	Not est.	0.1718	0.24 (0.03, 2.19)	0.24 (0.03, 2.19)	-2.2 (-5.4, 0.94)	4 (2.9)	7	1 (0.7)	1

Skin and subcutaneous tissue disorders
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

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Table 1.16.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Hand dermatitis									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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 1.16.721.4.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Germany					18	8.4		22	9.9	
Rest of World					119	57.0		116	55.5	

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 1.16.722.4.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Germany						18	8.4		22	9.9	
Rest of World						119	57.0		116	55.5	
Any system organ class											
Any preferred term											
Total	0.8821	0.8030	0.98 (0.87, 1.12)	0.93 (0.53, 1.64)	-1.3 (-11, 8.62)	107	(78.1)	391	106	(76.8)	361
Germany		0.8215	0.97 (0.78, 1.22)	0.80 (0.12, 5.37)	-2.4 (-23, 18.1)	16	(88.9)	45	19	(86.4)	57
Rest of World		0.7947	0.98 (0.85, 1.13)	0.92 (0.51, 1.68)	-1.5 (-12, 9.50)	91	(76.5)	346	87	(75.0)	304

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 1.16.723.4.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Germany						18 8.4		22 9.9	
Rest of World						119 57.0		116 55.5	
Any system organ class									
Any preferred term									
Total	Not est.	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5 (3.6)	8	1 (0.7)	1
Rest of World		0.1081	0.21 (0.03, 1.73)	0.20 (0.02, 1.74)	-3.3 (-7.3, 0.66)	5 (4.2)	8	1 (0.9)	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. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

Table 1.17.101.4.1.1: Total, Using RDCSA, Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	101	105
Age (years)		
Mean (sd)	33.2 (11.5)	35.7 (14.1)
Gender		
Female	40 (39.6%)	44 (41.9%)
Male	61 (60.4%)	61 (58.1%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	25.7 (6.1)	25.1 (4.2)
Race		
Asian	1 (1.0%)	
Black	1 (1.0%)	
White	99 (98.0%)	103 (98.1%)
Other		2 (1.9%)
Geographic region		
Europe	101 (100%)	105 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	57.3 (23.1)	55.3 (22.0)
Duration of AD (years)		
Mean (sd)	23.8 (12.5)	28.0 (13.4)
Eczema Area and Severity Index (EASI)		
Mean (sd)	34.5 (13.6)	32.7 (12.4)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	50 (49.5%)	50 (47.6%)
Severe [IGA=4]	51 (50.5%)	55 (52.4%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.5 (1.3)	7.3 (1.5)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	7.0 (1.6)	6.4 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	71.1 (12.9)	70.7 (12.4)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	16.6 (6.7)	15.9 (6.9)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	12.2 (7.8)	10.8 (6.6)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	52.4 (22.3)	56.3 (20.5)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.587 (0.25)	0.634 (0.24)
Patients that have tried systemic corticosteroids (%)		
No	33 (32.7%)	28 (26.7%)
Yes	68 (67.3%)	77 (73.3%)
Previous number of treatments with systemic immunosuppressants*		
0	2 (2.0%)	1 (1.0%)
1	67 (66.3%)	73 (69.5%)
2	23 (22.8%)	22 (21.0%)
3	6 (5.9%)	8 (7.6%)
4	2 (2.0%)	1 (1.0%)
5	1 (1.0%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

Table 1.17.101.4.2.1: Total, Not using RDCSA, Baseline characteristics of interest, LP0162-1346

	Placebo + TCS	Tralokinumab Q2W + TCS
Total		
N	36	33
Age (years)		
Mean (sd)	44.4 (15.9)	40.4 (16.0)
Gender		
Female	14 (38.9%)	13 (39.4%)
Male	22 (61.1%)	20 (60.6%)
Body mass index (BMI) (kg/m^2)		
Mean (sd)	26.0 (4.8)	25.1 (4.3)
Race		
White	36 (100%)	32 (97.0%)
Other		1 (3.0%)
Geographic region		
Europe	36 (100%)	33 (100%)
Body surface area (BSA) with AD (%)		
Mean (sd)	49.1 (21.2)	50.1 (21.2)
Duration of AD (years)		
Mean (sd)	29.8 (17.3)	24.0 (14.9)
Eczema Area and Severity Index (EASI)		
Mean (sd)	31.9 (13.2)	30.2 (8.2)
Investigator's Global Assessment (IGA)		
Moderate [IGA=3]	20 (55.6%)	18 (54.5%)
Severe [IGA=4]	16 (44.4%)	15 (45.5%)
Worst daily pruritus NRS (weekly average)		
Mean (sd)	7.4 (1.5)	7.0 (1.3)
Eczema-related sleep NRS (weekly average)		
Mean (sd)	6.8 (1.7)	6.1 (2.1)
Scoring Atopic Dermatitis (SCORAD)		
Mean (sd)	70.1 (12.8)	68.7 (10.9)
Dermatology Life Quality Index (DLQI)		
Mean (sd)	15.8 (5.2)	15.7 (5.3)
Hospital Anxiety and Depression Scale (HADS)		
Mean (sd)	10.7 (6.5)	10.3 (5.7)
EuroQoL 5-Dimension Health Questionnaire 5 Level (EQ-5D-5L) VAS		
Mean (sd)	52.8 (21.3)	57.4 (18.3)
EuroQoL 5-Dimension Health Questionnaire (EQ-5D) utility		
Mean (sd)	0.604 (0.20)	0.636 (0.18)
Patients that have tried systemic corticosteroids (%)		
No	13 (36.1%)	13 (39.4%)
Yes	23 (63.9%)	20 (60.6%)
Previous number of treatments with systemic immunosuppressants*		
0	21 (58.3%)	21 (63.6%)
1	11 (30.6%)	12 (36.4%)
2	4 (11.1%)	

Baseline characteristics are presented by randomized treatment and as total for the full analysis set. Numerical values are presented with mean and standard deviation. Categorical variables are presented with number of subjects and percentage of subjects. Q2W: Every 2 weeks. AD: Atopic Dermatitis. VAS: Visual Analogue Scale. Including subjects in the full analysis set. *Systemic immunosuppressants: Mycophenolate, Cyclosporine, Methotrexate, Azathioprine, Monoclonian antibody/Dupilumab. Including subjects in the full analysis set.

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Table 1.17.102.4.1: Total, Using RDCSA, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Using RDCSA				
Analysis set				
N	101		105	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	1	(1.0)		
Thrombocytopenia	1	(1.0)		
Eosinophilia			1	(1.0)
Iron deficiency anaemia			1	(1.0)
Lymphadenopathy			1	(1.0)
Cardiac disorders				
Sinus bradycardia	1	(1.0)	2	(1.9)
Atrioventricular block	1	(1.0)		
Bundle branch block right	1	(1.0)		
Bundle branch block left			1	(1.0)
Congestive cardiomyopathy			1	(1.0)
Mitral valve incompetence			1	(1.0)
Tachycardia			1	(1.0)
Congenital, familial and genetic disorders				
Congenital cystic kidney disease	1	(1.0)		
Gilbert's syndrome	1	(1.0)		
Sickle cell anaemia	1	(1.0)		
Von Willebrand's disease			1	(1.0)
Ear and labyrinth disorders				
Deafness neurosensory	1	(1.0)		
Tinnitus	1	(1.0)		
Endocrine disorders				
Hypothyroidism	2	(2.0)	4	(3.8)
Autoimmune thyroiditis	1	(1.0)		
Thyroid mass	1	(1.0)		
Goitre			1	(1.0)
Hyperprolactinaemia			1	(1.0)
Thyroiditis			1	(1.0)
Eye disorders				
Conjunctivitis allergic	30	(29.7)	28	(26.7)
Atopic keratoconjunctivitis	7	(6.9)	1	(1.0)
Keratoconus	2	(2.0)		
Myopia			2	(1.9)
Astigmatism	1	(1.0)		
Dry eye	1	(1.0)		
Glaucoma	1	(1.0)	1	(1.0)
Blepharitis			1	(1.0)
Cataract			1	(1.0)
Keratitis			1	(1.0)
Photophobia			1	(1.0)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	2	(2.0)	2	(1.9)
Dyspepsia			2	(1.9)
Chronic gastritis	1	(1.0)		
Crohn's disease	1	(1.0)		
Gastritis	1	(1.0)		
Haemorrhoids	1	(1.0)	1	(1.0)
Irritable bowel syndrome	1	(1.0)	1	(1.0)
Coeliac disease			1	(1.0)
Colitis ulcerative			1	(1.0)
Gastric ulcer			1	(1.0)
Hiatus hernia			1	(1.0)
Oesophagitis			1	(1.0)
General disorders and administration site conditions				
Xerosis	1	(1.0)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.17.102.4.1: Total, Using RDCSA, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Using RDCSA				
General disorders and administration site conditions				
Xerosis			2	(1.9)
Hernia	1	(1.0)		
Hepatobiliary disorders				
Hepatic steatosis			1	(1.0)
Immune system disorders				
Seasonal allergy	50	(49.5)	62	(59.0)
Food allergy	35	(34.7)	42	(40.0)
Allergy to animal	12	(11.9)	7	(6.7)
Mite allergy	11	(10.9)	8	(7.6)
Drug hypersensitivity	5	(5.0)	11	(10.5)
Multiple allergies	8	(7.9)	11	(10.5)
Hypersensitivity	4	(4.0)	3	(2.9)
Allergy to metals	1	(1.0)	3	(2.9)
Rubber sensitivity	1	(1.0)	3	(2.9)
Allergy to plants	2	(2.0)	2	(1.9)
Dust allergy			2	(1.9)
Allergy to chemicals	1	(1.0)	1	(1.0)
Flour sensitivity	1	(1.0)		
Mycotic allergy	1	(1.0)	1	(1.0)
Milk allergy			1	(1.0)
Oral allergy syndrome			1	(1.0)
Infections and infestations				
Herpes simplex	10	(9.9)	7	(6.7)
Oral herpes	1	(1.0)	2	(1.9)
Conjunctivitis	1	(1.0)		
Onychomycosis	1	(1.0)		
Sinusitis	1	(1.0)	1	(1.0)
Ear infection			1	(1.0)
Epididymitis			1	(1.0)
Rhinitis			1	(1.0)
Skin candida			1	(1.0)
Injury, poisoning and procedural complications				
Joint injury			1	(1.0)
Ligament sprain			1	(1.0)
Meniscus injury			1	(1.0)
Investigations				
Blood immunoglobulin E increased	1	(1.0)	1	(1.0)
Neutrophil count increased	1	(1.0)		
Vitamin B12 decreased	1	(1.0)		
White blood cell count increased	1	(1.0)		
Blood uric acid increased			1	(1.0)
Gamma-glutamyltransferase increased			1	(1.0)
Metabolism and nutrition disorders				
Hypercholesterolaemia	3	(3.0)	4	(3.8)
Dyslipidaemia	2	(2.0)		
Gout	2	(2.0)		
Lactose intolerance	2	(2.0)		
Obesity	2	(2.0)	2	(1.9)
Vitamin D deficiency	2	(2.0)	2	(1.9)
Diabetes mellitus			2	(1.9)
Glucose tolerance impaired	1	(1.0)		
Gluten sensitivity	1	(1.0)		
Hyperuricaemia	1	(1.0)	1	(1.0)
Iron deficiency	1	(1.0)		
Type 2 diabetes mellitus	1	(1.0)		
Histamine intolerance			1	(1.0)
Hyperinsulinism			1	(1.0)
Hyperlipidaemia			1	(1.0)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.17.102.4.1: Total, Using RDCSA, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Using RDCSA				
Metabolism and nutrition disorders				
Hypertriglyceridaemia			1	(1.0)
Purine metabolism disorder			1	(1.0)
Musculoskeletal and connective tissue disorders				
Back pain	1	(1.0)	4	(3.8)
Arthralgia	2	(2.0)		
Intervertebral disc protrusion	1	(1.0)	2	(1.9)
Osteoarthritis			2	(1.9)
Intervertebral disc disorder	1	(1.0)		
Joint range of motion decreased	1	(1.0)		
Myalgia	1	(1.0)		
Osteochondrosis	1	(1.0)		
Osteoporosis	1	(1.0)	1	(1.0)
Plica syndrome	1	(1.0)		
Temporomandibular joint syndrome	1	(1.0)		
Ankylosing spondylitis			1	(1.0)
Fibromyalgia			1	(1.0)
Lumbar spinal stenosis			1	(1.0)
Muscle spasms			1	(1.0)
Spinal pain			1	(1.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Melanocytic naevus			3	(2.9)
Haemangioma	1	(1.0)		
Fibroma			1	(1.0)
Haemangioma of liver			1	(1.0)
Skin papilloma			1	(1.0)
Nervous system disorders				
Headache	3	(3.0)	4	(3.8)
Migraine	2	(2.0)	3	(2.9)
Dysaesthesia	1	(1.0)		
Epilepsy	1	(1.0)		
Hydrocephalus	1	(1.0)		
Migraine with aura	1	(1.0)		
Narcolepsy	1	(1.0)		
Paralysis	1	(1.0)		
Restless legs syndrome	1	(1.0)		
Psychiatric disorders				
Anxiety			4	(3.8)
Depression	3	(3.0)	3	(2.9)
Insomnia	2	(2.0)	1	(1.0)
Depressed mood	1	(1.0)	1	(1.0)
Fear of injection	1	(1.0)		
Sleep disorder	1	(1.0)		
Affective disorder			1	(1.0)
Attention deficit/hyperactivity disorder			1	(1.0)
Stress			1	(1.0)
Renal and urinary disorders				
Proteinuria	3	(3.0)		
Haematuria	2	(2.0)		
Renal cyst	1	(1.0)		
Renal disorder	1	(1.0)		
Renal vein compression	1	(1.0)		
Chronic kidney disease			1	(1.0)
Nephrolithiasis			1	(1.0)
Renal failure			1	(1.0)
Reproductive system and breast disorders				
Benign prostatic hyperplasia	1	(1.0)	1	(1.0)
Dysmenorrhoea	1	(1.0)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.17.102.4.1: Total, Using RDCSA, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n (%)	Tralokinumab Q2W + TCS n (%)
Using RDCSA		
Reproductive system and breast disorders		
Dysmenorrhoea		1 (1.0)
Menstrual disorder	1 (1.0)	
Premenstrual syndrome	1 (1.0)	
Gynaecomastia		1 (1.0)
Ovarian cyst		1 (1.0)
Testicular cyst		1 (1.0)
Respiratory, thoracic and mediastinal disorders		
Asthma	52 (51.5)	47 (44.8)
Rhinitis allergic	14 (13.9)	7 (6.7)
Nasal septum deviation	2 (2.0)	2 (1.9)
Bronchial hyperreactivity	1 (1.0)	
Sinus disorder	1 (1.0)	
Dysphonia		1 (1.0)
Nasal turbinate hypertrophy		1 (1.0)
Skin and subcutaneous tissue disorders		
Alopecia areata	3 (3.0)	1 (1.0)
Alopecia	1 (1.0)	
Dermatitis contact	1 (1.0)	1 (1.0)
Photosensitivity reaction	1 (1.0)	
Psoriasis	1 (1.0)	
Skin sensitisation	1 (1.0)	
Urticaria	1 (1.0)	
Acne		1 (1.0)
Androgenetic alopecia		1 (1.0)
Vitiligo		1 (1.0)
Social circumstances		
Menopause		2 (1.9)
Postmenopause	1 (1.0)	
Surgical and medical procedures		
Female sterilisation	1 (1.0)	
Gastric bypass	1 (1.0)	
Maxillofacial operation	1 (1.0)	
Nasal septal operation	1 (1.0)	
Sterilisation	1 (1.0)	
Thyroid nodule removal	1 (1.0)	
Thyroidectomy	1 (1.0)	
Cardiac resynchronisation therapy		1 (1.0)
Contraception		1 (1.0)
Intra-uterine contraceptive device		1 (1.0)
Knee operation		1 (1.0)
Vascular disorders		
Hypertension	12 (11.9)	13 (12.4)
Varicose vein	1 (1.0)	1 (1.0)
Peripheral venous disease		1 (1.0)
Spider vein		1 (1.0)

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Table 1.17.102.4.1: Total, Not using RDCSA, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Not using RDCSA				
Analysis set				
N	36		33	
Blood and lymphatic system disorders				
Lymphopenia			1	(3.0)
Cardiac disorders				
Atrial fibrillation	1	(2.8)	2	(6.1)
Bundle branch block right	2	(5.6)		
Atrioventricular block first degree			1	(3.0)
Bradycardia			1	(3.0)
Atrial flutter	1	(2.8)		
Cardiomyopathy	1	(2.8)		
Myocardial infarction	1	(2.8)		
Myocardial ischaemia	1	(2.8)		
Congenital, familial and genetic disorders				
Benign familial haematuria	1	(2.8)		
Congenital anomaly	1	(2.8)		
Cytogenetic abnormality	1	(2.8)		
Ear and labyrinth disorders				
Deafness	1	(2.8)		
Endocrine disorders				
Hypothyroidism			5	(15.2)
Autoimmune thyroiditis	2	(5.6)		
Eye disorders				
Conjunctivitis allergic	11	(30.6)	12	(36.4)
Cataract			2	(6.1)
Atopic keratoconjunctivitis	2	(5.6)		
Dry eye	2	(5.6)		
Blepharitis			1	(3.0)
Retinal degeneration			1	(3.0)
Keratoconus	1	(2.8)		
Gastrointestinal disorders				
Gastrooesophageal reflux disease	1	(2.8)	2	(6.1)
Hiatus hernia	2	(5.6)		
Barrett's oesophagus	1	(2.8)	1	(3.0)
Chronic gastritis	1	(2.8)	1	(3.0)
Oesophagitis			1	(3.0)
Coeliac disease	1	(2.8)		
Irritable bowel syndrome	1	(2.8)		
General disorders and administration site conditions				
Xerosis			2	(6.1)
Dysplasia	1	(2.8)		
Oedema peripheral	1	(2.8)		
Immune system disorders				
Seasonal allergy	20	(55.6)	14	(42.4)
Food allergy	15	(41.7)	8	(24.2)
Mite allergy	5	(13.9)	6	(18.2)
Allergy to animal	5	(13.9)	3	(9.1)
Drug hypersensitivity	4	(11.1)	1	(3.0)
Allergy to chemicals			2	(6.1)
Allergy to metals			2	(6.1)
Allergy to plants	1	(2.8)	2	(6.1)
Milk allergy	1	(2.8)	2	(6.1)
Iodine allergy			1	(3.0)
Perfume sensitivity			1	(3.0)
Rubber sensitivity			1	(3.0)

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Table 1.17.102.4.1: Total, Not using RDCSA, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Not using RDCSA				
Immune system disorders				
Dust allergy	1	(2.8)		
Multiple allergies	1	(2.8)		
Infections and infestations				
Herpes simplex	1	(2.8)	6	(18.2)
Papilloma viral infection			1	(3.0)
Rhinitis			1	(3.0)
Sinusitis	1	(2.8)		
Injury, poisoning and procedural complications				
Scar			2	(6.1)
Deafness traumatic	1	(2.8)		
Investigations				
Aspartate aminotransferase increased	1	(2.8)		
Gamma-glutamyltransferase increased	1	(2.8)		
Lymph node palpable	1	(2.8)		
Mean cell volume increased	1	(2.8)		
Metabolism and nutrition disorders				
Diabetes mellitus			2	(6.1)
Gluten sensitivity	2	(5.6)		
Hyperlipidaemia	2	(5.6)		
Dyslipidaemia	1	(2.8)	1	(3.0)
Hypercholesterolaemia			1	(3.0)
Hyperuricaemia			1	(3.0)
Iron deficiency			1	(3.0)
Overweight			1	(3.0)
Gout	1	(2.8)		
Lactose intolerance	1	(2.8)		
Mineral deficiency	1	(2.8)		
Musculoskeletal and connective tissue disorders				
Osteoarthritis	2	(5.6)	1	(3.0)
Osteopenia	2	(5.6)		
Back pain			1	(3.0)
Foot deformity			1	(3.0)
Intervertebral disc protrusion	1	(2.8)	1	(3.0)
Osteoporosis			1	(3.0)
Arthralgia	1	(2.8)		
Growth retardation	1	(2.8)		
Myalgia	1	(2.8)		
Spinal osteoarthritis	1	(2.8)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Blepharal papilloma			1	(3.0)
Melanocytic naevus			1	(3.0)
Nervous system disorders				
Headache	2	(5.6)	3	(9.1)
Migraine	3	(8.3)	3	(9.1)
Hypertonia			2	(6.1)
Multiple sclerosis	1	(2.8)		
Restless legs syndrome	1	(2.8)		
Psychiatric disorders				
Anxiety	1	(2.8)	1	(3.0)
Depressed mood			1	(3.0)
Sleep disorder			1	(3.0)
Depression	1	(2.8)		
Eating disorder	1	(2.8)		
Nervousness	1	(2.8)		

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Table 1.17.102.4.1: Total, Not using RDCSA, Current medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Not using RDCSA				
Renal and urinary disorders				
IgA nephropathy			1	(3.0)
Nephrolithiasis			1	(3.0)
Incontinence	1	(2.8)		
Proteinuria	1	(2.8)		
Renal failure	1	(2.8)		
Reproductive system and breast disorders				
Benign prostatic hyperplasia	1	(2.8)		
Erectile dysfunction	1	(2.8)		
Polycystic ovaries	1	(2.8)		
Respiratory, thoracic and mediastinal disorders				
Asthma	22	(61.1)	15	(45.5)
Rhinitis allergic	6	(16.7)	2	(6.1)
Chronic obstructive pulmonary disease			2	(6.1)
Bronchiectasis			1	(3.0)
Bronchitis chronic			1	(3.0)
Sleep apnoea syndrome			1	(3.0)
Nasal polyps	1	(2.8)		
Skin and subcutaneous tissue disorders				
Acne			1	(3.0)
Photosensitivity reaction			1	(3.0)
Rosacea			1	(3.0)
Urticaria			1	(3.0)
Alopecia	1	(2.8)		
Vitiligo	1	(2.8)		
Surgical and medical procedures				
Cardiac pacemaker insertion			1	(3.0)
Lip lesion excision	1	(2.8)		
Vascular disorders				
Hypertension	13	(36.1)	10	(30.3)
Peripheral venous disease	2	(5.6)	2	(6.1)

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Table 1.17.103.4.1: Total, Using RDCSA, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Using RDCSA				
Analysis set				
N	101		105	
Blood and lymphatic system disorders				
Normochromic normocytic anaemia	2	(2.0)		
Iron deficiency anaemia	1	(1.0)		
Cardiac disorders				
Myocardial ischaemia			1	(1.0)
Pericarditis			1	(1.0)
Congenital, familial and genetic disorders				
Phimosis			2	(1.9)
Endocrine disorders				
Basedow's disease	1	(1.0)		
Goitre	1	(1.0)		
Thyroid mass			1	(1.0)
Eye disorders				
Conjunctivitis allergic	2	(2.0)	2	(1.9)
Cataract	1	(1.0)	1	(1.0)
Corneal oedema	1	(1.0)		
Keratitis	1	(1.0)	1	(1.0)
Atopic keratoconjunctivitis			1	(1.0)
Keratoconus			1	(1.0)
Gastrointestinal disorders				
Gastrooesophageal reflux disease	1	(1.0)		
Pancreatitis acute	1	(1.0)		
Hiatus hernia			1	(1.0)
Inguinal hernia			1	(1.0)
Intestinal obstruction			1	(1.0)
Proctitis			1	(1.0)
General disorders and administration site conditions				
Hernia			1	(1.0)
Immune system disorders				
Seasonal allergy			2	(1.9)
Corneal graft rejection	1	(1.0)		
Oral allergy syndrome	1	(1.0)		
Mite allergy			1	(1.0)
Infections and infestations				
Herpes simplex	2	(2.0)	7	(6.7)
Impetigo	6	(5.9)	5	(4.8)
Eczema herpeticum	4	(4.0)	2	(1.9)
Herpes zoster	4	(4.0)	4	(3.8)
Infectious mononucleosis	2	(2.0)		
Meningitis	2	(2.0)		
Meningitis viral			2	(1.9)
Varicella			2	(1.9)
Appendicitis	1	(1.0)		
Enterobiasis	1	(1.0)		
Epiglottitis	1	(1.0)		
Furuncle	1	(1.0)		
Helicobacter gastritis	1	(1.0)		
Ophthalmic herpes simplex	1	(1.0)		
Oral herpes	1	(1.0)		
Otitis externa	1	(1.0)		
Pilonidal cyst	1	(1.0)		
Pneumonia	1	(1.0)		
Postoperative wound infection	1	(1.0)		

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Table 1.17.103.4.1: Total, Using RDCSA, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Using RDCSA				
Infections and infestations				
Rhinitis	1	(1.0)		
Skin bacterial infection	1	(1.0)		
Tuberculosis	1	(1.0)		
Conjunctivitis			1	(1.0)
Erysipelas			1	(1.0)
Groin abscess			1	(1.0)
Herpes ophthalmic			1	(1.0)
Infection parasitic			1	(1.0)
Myringitis			1	(1.0)
Otitis media			1	(1.0)
Staphylococcal skin infection			1	(1.0)
Vaginal infection			1	(1.0)
Vulvovaginal candidiasis			1	(1.0)
Injury, poisoning and procedural complications				
Upper limb fracture	1	(1.0)	2	(1.9)
Chillblains	1	(1.0)		
Femur fracture	1	(1.0)		
Hand fracture	1	(1.0)		
Humerus fracture	1	(1.0)		
Joint dislocation	1	(1.0)		
Joint injury	1	(1.0)		
Ligament injury	1	(1.0)		
Ligament rupture	1	(1.0)		
Wound secretion	1	(1.0)		
Comminuted fracture			1	(1.0)
Facial bones fracture			1	(1.0)
Foot fracture			1	(1.0)
Ligament sprain			1	(1.0)
Limb fracture			1	(1.0)
Post-traumatic neck syndrome			1	(1.0)
Spinal fracture			1	(1.0)
Tibia fracture			1	(1.0)
Wrist fracture			1	(1.0)
Investigations				
Biopsy breast	1	(1.0)		
Biopsy lymph gland	1	(1.0)		
Metabolism and nutrition disorders				
Hypoproteinaemia	1	(1.0)		
Starvation	1	(1.0)		
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion	1	(1.0)		
Osteochondrosis	1	(1.0)		
Foot deformity			1	(1.0)
Joint contracture			1	(1.0)
Lumbar spinal stenosis			1	(1.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acanthoma	1	(1.0)		
Anogenital warts	1	(1.0)		
Benign pancreatic neoplasm	1	(1.0)		
Melanocytic naevus	1	(1.0)		
Papilloma	1	(1.0)		
Skin papilloma	1	(1.0)		
Nervous system disorders				
Epilepsy	1	(1.0)		
Migraine	1	(1.0)	1	(1.0)
Restless legs syndrome	1	(1.0)		
Cerebral ischaemia			1	(1.0)

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Table 1.17.103.4.1: Total, Using RDCSA, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Using RDCSA				
Pregnancy, puerperium and perinatal conditions				
HELLP syndrome	1	(1.0)		
Psychiatric disorders				
Depression	2	(2.0)	5	(4.8)
Drug use disorder	1	(1.0)		
Insomnia	1	(1.0)		
Mood altered	1	(1.0)		
Stress	1	(1.0)		
Adjustment disorder with depressed mood			1	(1.0)
Panic attack			1	(1.0)
Renal and urinary disorders				
Hydronephrosis	1	(1.0)		
Nephrolithiasis	1	(1.0)		
Renal colic			1	(1.0)
Ureterolithiasis			1	(1.0)
Reproductive system and breast disorders				
Acquired phimosis	1	(1.0)		
Breast cyst	1	(1.0)		
Polycystic ovaries	1	(1.0)		
Varicocele			1	(1.0)
Respiratory, thoracic and mediastinal disorders				
Asthma	2	(2.0)	7	(6.7)
Rhinitis allergic	2	(2.0)		
Bronchospasm			1	(1.0)
Pulmonary embolism			1	(1.0)
Skin and subcutaneous tissue disorders				
Acne	1	(1.0)	1	(1.0)
Acne conglobata	1	(1.0)		
Dermatitis exfoliative	1	(1.0)		
Rosacea	1	(1.0)		
Alopecia			1	(1.0)
Alopecia areata			1	(1.0)
Angioedema			1	(1.0)
Dermatitis contact			1	(1.0)
Hidradenitis			1	(1.0)
Ingrowing nail			1	(1.0)
Purpura			1	(1.0)
Seborrhoeic dermatitis			1	(1.0)
Surgical and medical procedures				
Tonsillectomy	1	(1.0)	5	(4.8)
Hysterectomy			3	(2.9)
Adenoidectomy	2	(2.0)	2	(1.9)
Caesarean section	2	(2.0)	1	(1.0)
Cholecystectomy	2	(2.0)	1	(1.0)
Ligament operation	2	(2.0)	2	(1.9)
Nasal septal operation	2	(2.0)	1	(1.0)
Appendicectomy	1	(1.0)	2	(1.9)
Arthrodesis			2	(1.9)
Cataract operation			2	(1.9)
UV light therapy			2	(1.9)
Benign tumour excision	1	(1.0)		
Carpal tunnel decompression	1	(1.0)	1	(1.0)
Cyst removal	1	(1.0)	1	(1.0)
Endometrial ablation	1	(1.0)		
Eye laser surgery	1	(1.0)		
Finger amputation	1	(1.0)		
Hernia repair	1	(1.0)		
Keratoplasty	1	(1.0)		

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Table 1.17.103.4.1: Total, Using RDCSA, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Using RDCSA				
Surgical and medical procedures				
Large intestinal polypectomy	1	(1.0)		
Meniscus operation	1	(1.0)	1	(1.0)
Myringotomy	1	(1.0)		
Ovarian cystectomy	1	(1.0)		
Polypectomy	1	(1.0)		
Prophylaxis	1	(1.0)		
Sinus operation	1	(1.0)		
Small intestinal resection	1	(1.0)		
Strabismus correction	1	(1.0)		
Tooth extraction	1	(1.0)	1	(1.0)
Tumour excision	1	(1.0)		
Turbinoplasty	1	(1.0)	1	(1.0)
Ventriculo-peritoneal shunt	1	(1.0)		
Wisdom teeth removal	1	(1.0)	1	(1.0)
Abscess drainage			1	(1.0)
Adrenalectomy			1	(1.0)
Amygdalotomy			1	(1.0)
Bunion operation			1	(1.0)
Cervical conisation			1	(1.0)
Circumcision			1	(1.0)
Female sterilisation			1	(1.0)
Fracture treatment			1	(1.0)
Hospitalisation			1	(1.0)
Knee operation			1	(1.0)
Lip lesion excision			1	(1.0)
Meniscus removal			1	(1.0)
Myopia correction			1	(1.0)
Nasal polypectomy			1	(1.0)
Nephrectomy			1	(1.0)
Skin neoplasm excision			1	(1.0)
Thyroidectomy			1	(1.0)
Vascular disorders				
Infarction			1	(1.0)

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Table 1.17.103.4.1: Total, Not using RDCSA, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Not using RDCSA				
Analysis set				
N	36		33	
Blood and lymphatic system disorders				
Neutropenia	1	(2.8)		
Cardiac disorders				
Bundle branch block left	1	(2.8)		
Cardiac failure	1	(2.8)		
Eye disorders				
Cataract			2	(6.1)
Conjunctivitis allergic	2	(5.6)	1	(3.0)
Retinal detachment			1	(3.0)
Lacrimation increased	1	(2.8)		
Gastrointestinal disorders				
Haemorrhoids			1	(3.0)
General disorders and administration site conditions				
Hypothermia			1	(3.0)
Dysplasia	1	(2.8)		
Immune system disorders				
Hypersensitivity	1	(2.8)		
Infections and infestations				
Impetigo	4	(11.1)		
Herpes zoster	2	(5.6)	2	(6.1)
Eczema herpeticum	2	(5.6)		
Varicella	2	(5.6)		
Bacterial infection			1	(3.0)
Cellulitis			1	(3.0)
Erysipelas			1	(3.0)
Post procedural infection			1	(3.0)
Appendicitis	1	(2.8)		
Conjunctivitis	1	(2.8)		
Dermatitis infected	1	(2.8)		
Herpes simplex	1	(2.8)		
Mumps	1	(2.8)		
Ophthalmic herpes simplex	1	(2.8)		
Oral herpes	1	(2.8)		
Pyelonephritis	1	(2.8)		
Staphylococcal infection	1	(2.8)		
Tinea cruris	1	(2.8)		
Upper respiratory tract infection	1	(2.8)		
Urinary tract infection	1	(2.8)		
Injury, poisoning and procedural complications				
Ankle fracture			1	(3.0)
Clavicle fracture	1	(2.8)		
Facial bones fracture	1	(2.8)		
Joint injury	1	(2.8)		
Meniscus injury	1	(2.8)		
Multiple fractures	1	(2.8)		
Upper limb fracture	1	(2.8)		
Investigations				
Arthroscopy	1	(2.8)		
Skin test	1	(2.8)		
Metabolism and nutrition disorders				
Lactose intolerance			1	(3.0)
Musculoskeletal and connective tissue disorders				
Bursitis	1	(2.8)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.17.103.4.1: Total, Not using RDCSA, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Not using RDCSA				
Musculoskeletal and connective tissue disorders				
Osteoarthritis	1	(2.8)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Bladder transitional cell carcinoma			1	(3.0)
Hodgkin's disease			1	(3.0)
Renal cancer			1	(3.0)
Sweat gland tumour			1	(3.0)
Testis cancer			1	(3.0)
Anogenital warts	1	(2.8)		
Basal cell carcinoma	1	(2.8)		
Bowen's disease	1	(2.8)		
Breast cancer	1	(2.8)		
Prostate cancer	1	(2.8)		
Squamous cell carcinoma of skin	1	(2.8)		
Nervous system disorders				
Paraesthesia			1	(3.0)
Seizure			1	(3.0)
Epilepsy	1	(2.8)		
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous	1	(2.8)		
Psychiatric disorders				
Anxiety			1	(3.0)
Alcoholism	1	(2.8)		
Renal and urinary disorders				
Acute kidney injury	1	(2.8)		
Nephrolithiasis	1	(2.8)		
Reproductive system and breast disorders				
Ovarian cyst			1	(3.0)
Sexual dysfunction			1	(3.0)
Respiratory, thoracic and mediastinal disorders				
Asthma			1	(3.0)
Pneumothorax			1	(3.0)
Rhinitis allergic			1	(3.0)
Maxillary sinus pseudocyst	1	(2.8)		
Skin and subcutaneous tissue disorders				
Dermatitis contact	2	(5.6)		
Alopecia			1	(3.0)
Dermal cyst	1	(2.8)		
Surgical and medical procedures				
Tonsillectomy			4	(12.1)
Appendicectomy	3	(8.3)	1	(3.0)
Caesarean section	1	(2.8)	2	(6.1)
Hysterectomy	2	(5.6)		
Immunisation	2	(5.6)		
Abscess drainage			1	(3.0)
Cataract operation			1	(3.0)
Cyst removal			1	(3.0)
Eye operation			1	(3.0)
Female genital operation			1	(3.0)
Hepatitis B immunisation			1	(3.0)
Inguinal hernia repair	1	(2.8)	1	(3.0)
Knee operation			1	(3.0)
Nephrectomy			1	(3.0)
Oophorectomy			1	(3.0)
Pleurodesis			1	(3.0)

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.17.103.4.1: Total, Not using RDCSA, Past medical history by SOC and Preferred term, LP0162-1346

SOC/PT	Placebo + TCS n	Placebo + TCS (%)	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)
Not using RDCSA				
Surgical and medical procedures				
Turbinoplasty			1	(3.0)
Adenoidectomy	1	(2.8)		
Cardiac ablation	1	(2.8)		
Cholecystectomy	1	(2.8)		
In vitro fertilisation	1	(2.8)		
Jaw operation	1	(2.8)		
Ligament operation	1	(2.8)		
Oral surgery	1	(2.8)		
Pneumococcal immunisation	1	(2.8)		
Shoulder operation	1	(2.8)		
Spinal operation	1	(2.8)		
Stent placement	1	(2.8)		
Varicose vein operation	1	(2.8)		
Vascular disorders				
Thrombophlebitis	1	(2.8)	1	(3.0)
Hypertension	1	(2.8)		

The number of subjects, percentage of subjects and number of events are summarised by preferred term and presented by treatment. N: Number of exposed subjects, n: number of subjects with an event. %: percent of subjects with an event. Q2W: Every 2 weeks. SOC: System organ class, PT: Preferred term. MH: medical history

Table 1.17.104.4.1: Total, Using RDCSA, Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	105 (100.0)	101 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	29 (27.6)	30 (29.7)
More than 3	18 (17.1)	23 (22.8)
Never	57 (54.3)	55 (54.5)
Past	16 (15.2)	15 (14.9)
More than 3	11 (10.5)	8 (7.9)
Unknown	3 (2.9)	1 (1.0)
ASTHMA		
Current	47 (44.8)	52 (51.5)
Never	46 (43.8)	44 (43.6)
Past	12 (11.4)	5 (5.0)
ATOPIC KERATOCONJUNCTIVITIS		
Current		7 (6.9)
More than 3		4 (4.0)
Never	98 (93.3)	85 (84.2)
Past	4 (3.8)	7 (6.9)
More than 3		2 (2.0)
Unknown	3 (2.9)	2 (2.0)
ECZEMA HERPETICUM		
Never	89 (84.8)	87 (86.1)
Past	13 (12.4)	11 (10.9)
More than 3	4 (3.8)	3 (3.0)
Unknown	3 (2.9)	3 (3.0)
FOOD ALLERGY		
Current	49 (46.7)	38 (37.6)
Never	54 (51.4)	59 (58.4)
Past	1 (1.0)	2 (2.0)
Unknown	1 (1.0)	2 (2.0)
HAY FEVER		
Current	61 (58.1)	55 (54.5)
Never	38 (36.2)	38 (37.6)
Past	6 (5.7)	5 (5.0)
Unknown		3 (3.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.17.104.4.1: Total, Not using RDCSA, Atopy history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	33 (100.0)	36 (100.0)
ALLERGIC CONJUNCTIVITIS		
Current	12 (36.4)	11 (30.6)
More than 3	6 (18.2)	6 (16.7)
Never	15 (45.5)	19 (52.8)
Past	6 (18.2)	6 (16.7)
More than 3	1 (3.0)	4 (11.1)
ASTHMA		
Current	15 (45.5)	22 (61.1)
Never	17 (51.5)	14 (38.9)
Past	1 (3.0)	
ATOPIC KERATOCONJUNCTIVITIS		
Current		2 (5.6)
More than 3		1 (2.8)
Never	33 (100.0)	32 (88.9)
Past		2 (5.6)
More than 3		1 (2.8)
ECZEMA HERPETICUM		
Never	32 (97.0)	31 (86.1)
Past	1 (3.0)	4 (11.1)
Unknown		1 (2.8)
FOOD ALLERGY		
Current	7 (21.2)	17 (47.2)
Never	24 (72.7)	18 (50.0)
Past	1 (3.0)	
Unknown	1 (3.0)	1 (2.8)
HAY FEVER		
Current	15 (45.5)	22 (61.1)
Never	13 (39.4)	14 (38.9)
Past	4 (12.1)	
Unknown	1 (3.0)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.17.105.4.1: Total, Using RDCSA, Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	105 (100.0)	101 (100.0)
ALOPECIA		
Current	2 (1.9)	4 (4.0)
Never	101 (96.2)	95 (94.1)
Past	1 (1.0)	1 (1.0)
Unknown	1 (1.0)	1 (1.0)
CELLULITIS		
Never	99 (94.3)	96 (95.0)
Past	2 (1.9)	5 (5.0)
Unknown	4 (3.8)	
HERPES SIMPLEX		
Current	8 (7.6)	11 (10.9)
More than 3	4 (3.8)	7 (6.9)
Never	68 (64.8)	65 (64.4)
Past	25 (23.8)	24 (23.8)
More than 3	11 (10.5)	15 (14.9)
Unknown	4 (3.8)	1 (1.0)
IMPETIGO		
Never	79 (75.2)	75 (74.3)
Past	23 (21.9)	24 (23.8)
More than 3	7 (6.7)	10 (9.9)
Unknown	3 (2.9)	2 (2.0)
OTHER SKIN INFECTIONS		
Never	93 (88.6)	88 (87.1)
Past	5 (4.8)	10 (9.9)
Unknown	7 (6.7)	3 (3.0)
VITILIGO		
Current	1 (1.0)	
Never	103 (98.1)	101 (100.0)
Unknown	1 (1.0)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.17.105.4.1: Total, Not using RDCSA, Skin disease history, LP0162-1346

Term Period Number	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	33 (100.0)	36 (100.0)
ALOPECIA		
Current		1 (2.8)
Never	32 (97.0)	35 (97.2)
Past	1 (3.0)	
CELLULITIS		
Never	31 (93.9)	34 (94.4)
Past	1 (3.0)	2 (5.6)
Unknown	1 (3.0)	
HERPES SIMPLEX		
Current	6 (18.2)	1 (2.8)
More than 3	3 (9.1)	1 (2.8)
Never	24 (72.7)	24 (66.7)
Past	3 (9.1)	11 (30.6)
More than 3	1 (3.0)	8 (22.2)
IMPETIGO		
Never	29 (87.9)	24 (66.7)
Past	4 (12.1)	12 (33.3)
More than 3	1 (3.0)	3 (8.3)
OTHER SKIN INFECTIONS		
Never	24 (72.7)	29 (80.6)
Past	7 (21.2)	5 (13.9)
Unknown	2 (6.1)	2 (5.6)
VITILIGO		
Current		1 (2.8)
Never	32 (97.0)	35 (97.2)
Past	1 (3.0)	

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s). MH: medical history

Table 1.17.107.4.1: Total, Using RDCSA, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	105 (100.0)	101 (100.0)
Antibiotics		
Yes	40 (38.1)	48 (47.5)
No	60 (57.1)	49 (48.5)
Unknown	5 (4.8)	4 (4.0)
Azathioprine		
Yes	15 (14.3)	13 (12.9)
More than 12 weeks?		
Yes	12 (11.4)	7 (6.9)
No	3 (2.9)	3 (3.0)
Unknown		3 (3.0)
Reason for discontinuation		
Inadequate efficacy	10 (9.5)	10 (9.9)
Other	1 (1.0)	2 (2.0)
Side effects	4 (3.8)	1 (1.0)
No	85 (81.0)	85 (84.2)
Reason for not using		
Contraindications	1 (1.0)	5 (5.0)
Risk of side effects	33 (31.4)	22 (21.8)
Other	51 (48.6)	58 (57.4)
Unknown	5 (4.8)	3 (3.0)
Cyclosporine		
Yes	104 (99.0)	99 (98.0)
More than 12 weeks?		
Yes	70 (66.7)	70 (69.3)
No	34 (32.4)	28 (27.7)
Unknown		1 (1.0)
Reason for discontinuation		
Treatment duration >	5 (4.8)	7 (6.9)
Inadequate efficacy	51 (48.6)	43 (42.6)
Other	7 (6.7)	7 (6.9)
Side effects	41 (39.0)	42 (41.6)
No	1 (1.0)	2 (2.0)
Reason for not using		
Contraindications	1 (1.0)	1 (1.0)
Other		1 (1.0)
Methotrexate		
Yes	19 (18.1)	21 (20.8)
More than 12 weeks?		
Yes	13 (12.4)	15 (14.9)
No	6 (5.7)	5 (5.0)
Unknown		1 (1.0)
Reason for discontinuation		
Inadequate efficacy	12 (11.4)	15 (14.9)
Other	1 (1.0)	
Side effects	6 (5.7)	6 (5.9)
No	84 (80.0)	78 (77.2)
Reason for not using		
Contraindications	4 (3.8)	4 (4.0)
Risk of side effects	31 (29.5)	20 (19.8)
Other	49 (46.7)	54 (53.5)
Unknown	2 (1.9)	2 (2.0)
Monoclonal antibody/Dupilumab		

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.17.107.4.1: Total, Using RDCSA, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Yes	4 (3.8)	6 (5.9)
No	99 (94.3)	94 (93.1)
Unknown	2 (1.9)	1 (1.0)
Mycophenolate		
Yes	3 (2.9)	5 (5.0)
More than 12 weeks?		
Yes	3 (2.9)	1 (1.0)
No		4 (4.0)
Reason for discontinuation		
Inadequate efficacy	3 (2.9)	3 (3.0)
Side effects		2 (2.0)
No	97 (92.4)	93 (92.1)
Reason for not using		
Contraindications	2 (1.9)	3 (3.0)
Risk of side effects	32 (30.5)	24 (23.8)
Other	62 (59.0)	66 (65.3)
Unknown	5 (4.8)	3 (3.0)
Other immunosuppressant		
Yes	15 (14.3)	9 (8.9)
No	88 (83.8)	90 (89.1)
Unknown	2 (1.9)	2 (2.0)
Phototherapy		
Yes	61 (58.1)	68 (67.3)
No	43 (41.0)	33 (32.7)
Unknown	1 (1.0)	
Systemic steroids		
Yes	77 (73.3)	68 (67.3)
No	26 (24.8)	27 (26.7)
Unknown	2 (1.9)	6 (5.9)
Topical calcineurin inhibitor		
Yes	69 (65.7)	73 (72.3)
No	31 (29.5)	26 (25.7)
Unknown	5 (4.8)	2 (2.0)
Topical corticosteroids		
Yes	105 (100.0)	100 (99.0)
Highest potency		
High	55 (52.4)	37 (36.6)
Low		1 (1.0)
Moderate	10 (9.5)	9 (8.9)
Ultra high	33 (31.4)	51 (50.5)
Unknown	7 (6.7)	2 (2.0)
No		1 (1.0)
Wet wraps		
Yes	15 (14.3)	14 (13.9)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.17.107.4.1: Total, Using RDCSA, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
No	82 (78.1)	86 (85.1)
Unknown	8 (7.6)	1 (1.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.17.107.4.1: Total, Not using RDCSA, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Total	33 (100.0)	36 (100.0)
Antibiotics		
Yes	15 (45.5)	18 (50.0)
No	16 (48.5)	13 (36.1)
Unknown	2 (6.1)	5 (13.9)
Azathioprine		
Yes	3 (9.1)	5 (13.9)
More than 12 weeks?		
Yes	1 (3.0)	5 (13.9)
No	1 (3.0)	
Unknown	1 (3.0)	
Reason for discontinuation		
Inadequate efficacy	2 (6.1)	4 (11.1)
Side effects	1 (3.0)	1 (2.8)
No	29 (87.9)	31 (86.1)
Reason for not using		
Contraindications	4 (12.1)	5 (13.9)
Risk of side effects	11 (33.3)	11 (30.6)
Other	14 (42.4)	15 (41.7)
Unknown	1 (3.0)	
Cyclosporine		
Yes		3 (8.3)
More than 12 weeks?		
Yes		1 (2.8)
No		2 (5.6)
Reason for discontinuation		
Side effects		3 (8.3)
No	33 (100.0)	33 (91.7)
Reason for not using		
Contraindications	27 (81.8)	23 (63.9)
Risk of side effects	4 (12.1)	4 (11.1)
Other	2 (6.1)	6 (16.7)
Methotrexate		
Yes	4 (12.1)	5 (13.9)
More than 12 weeks?		
Yes	2 (6.1)	3 (8.3)
No	2 (6.1)	2 (5.6)
Reason for discontinuation		
Inadequate efficacy	3 (9.1)	3 (8.3)
Other		2 (5.6)
Side effects	1 (3.0)	
No	29 (87.9)	31 (86.1)
Reason for not using		
Contraindications	7 (21.2)	8 (22.2)
Risk of side effects	8 (24.2)	12 (33.3)
Other	14 (42.4)	11 (30.6)
Monoclonal antibody/Dupilumab		
Yes	5 (15.2)	6 (16.7)
No	28 (84.8)	30 (83.3)
Mycophenolate		
No	30 (90.9)	36 (100.0)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

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Table 1.17.107.4.1: Total, Not using RDCSA, Previous AD treatments, LP0162-1346

	Tralokinumab Q2W + TCS N (%)	Placebo + TCS N (%)
Reason for not using		
Contraindications	2 (6.1)	5 (13.9)
Risk of side effects	13 (39.4)	10 (27.8)
Other	15 (45.5)	21 (58.3)
Unknown	3 (9.1)	
Other immunosuppressant		
Yes	1 (3.0)	3 (8.3)
No	32 (97.0)	33 (91.7)
Phototherapy		
Yes	18 (54.5)	16 (44.4)
No	15 (45.5)	20 (55.6)
Systemic steroids		
Yes	20 (60.6)	23 (63.9)
No	10 (30.3)	12 (33.3)
Unknown	3 (9.1)	1 (2.8)
Topical calcineurin inhibitor		
Yes	23 (69.7)	22 (61.1)
No	6 (18.2)	14 (38.9)
Unknown	4 (12.1)	
Topical corticosteroids		
Yes	33 (100.0)	36 (100.0)
Highest potency		
High	21 (63.6)	17 (47.2)
Moderate		6 (16.7)
Ultra high	10 (30.3)	12 (33.3)
Unknown	2 (6.1)	1 (2.8)
Wet wraps		
Yes	10 (30.3)	5 (13.9)
No	22 (66.7)	28 (77.8)
Unknown	1 (3.0)	3 (8.3)

%: percentage of subjects, n: number of subjects, Q2W: every 2 weeks, TCS: topical corticosteroid(s).

Table 1.17.325.4.1: Total, RDSCA Use, EASI 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	88 (63.8)	15.3 (3.72;26.79)	1.3 (1.06; 1.62)	1.9 (1.16; 3.05)	0.0104	0.8747
Placebo + TCS	137	67 (48.9)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	25 (75.8)	11.9 (-9.53;33.33)	1.2 (0.87; 1.62)	1.8 (0.62; 5.05)	0.2899	
Placebo + TCS	36	23 (63.9)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	63 (60.0)	16.4 (2.75;29.99)	1.4 (1.05; 1.81)	1.9 (1.10; 3.30)	0.0192	
Placebo + TCS	101	44 (43.6)					

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 Prior CSA use and baseline IGA.

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Table 1.17.326.4.1: Total, RDSCA Use, EASI 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	57 (41.3)	14.2 (3.21;25.12)	1.5 (1.09; 2.10)	1.9 (1.15; 3.21)	0.0123	0.1511
Placebo + TCS	137	38 (27.7)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	22 (66.7)	30.7 (8.13;53.19)	1.8 (1.12; 3.04)	3.5 (1.30; 9.52)	0.0117	
Placebo + TCS	36	13 (36.1)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	35 (33.3)	8.7 (-3.70;21.00)	1.3 (0.87; 2.08)	1.5 (0.83; 2.79)	0.1736	
Placebo + TCS	101	25 (24.8)					

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 Prior CSA use and baseline IGA.

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Table 1.17.329.4.1: Total, RDSCA Use, SCORAD 75, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	40 (29.0)	16.9 (7.55;26.16)	2.4 (1.42; 3.96)	3.0 (1.58; 5.62)	0.0006	0.8183
Placebo + TCS	137	17 (12.4)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	13 (39.4)	20.0 (-1.15;41.05)	2.0 (0.92; 4.46)	2.7 (0.91; 7.94)	0.0722	
Placebo + TCS	36	7 (19.4)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	27 (25.7)	15.8 (5.61;26.03)	2.6 (1.32; 5.07)	3.1 (1.43; 6.86)	0.0033	
Placebo + TCS	101	10 (9.9)					

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 Prior CSA use and baseline IGA.

17FEB21 16:58 LP0162-Payer /p_bin_eff1/T_t_csa_f29_46_w16.txt

Table 1.17.330.4.1: Total, RDSCA Use, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	134	62 (46.3)	9.7 (-1.99;21.41)	1.3 (0.95; 1.69)	1.5 (0.92; 2.44)	0.1068	0.6522
Placebo + TCS	135	49 (36.3)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	15 (45.5)	5.4 (-18.3;29.12)	1.1 (0.65; 1.99)	1.2 (0.48; 3.23)	0.6561	
Placebo + TCS	35	14 (40.0)					
Using RDCSA							
Tralokinumab Q2W + TCS	101	47 (46.5)	11.2 (-2.28;24.60)	1.3 (0.94; 1.84)	1.6 (0.90; 2.83)	0.1071	
Placebo + TCS	100	35 (35.0)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

17FEB21 17:00 LP0162-Payer /p_bin_eff1/T_t_csa_f30_46_w16.txt

Table 1.17.331.4.1: Total, RDSCA Use, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	137	85 (62.0)	11.3 (-0.46;23.02)	1.2 (0.99; 1.51)	1.6 (0.98; 2.55)	0.0614	0.3823
Placebo + TCS	136	69 (50.7)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	20 (60.6)	2.4 (-21.2;25.89)	1.0 (0.70; 1.55)	1.1 (0.43; 2.84)	0.8439	
Placebo + TCS	36	21 (58.3)					
Using RDCSA							
Tralokinumab Q2W + TCS	104	65 (62.5)	14.3 (0.80;27.79)	1.3 (1.01; 1.67)	1.8 (1.03; 3.14)	0.0405	
Placebo + TCS	100	48 (48.0)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 3.

17FEB21 17:00 LP0162-Payer /p_bin_eff1/T_t_csa_f31_46_w16.txt

Table 1.17.333.4.1: Total, RDSCA Use, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	135	105 (77.8)	18.9 (8.08;29.81)	1.3 (1.12; 1.56)	2.5 (1.44; 4.20)	0.0009	0.8131
Placebo + TCS	134	79 (59.0)					
Not using RDCSA							
Tralokinumab Q2W + TCS	32	26 (81.3)	20.2 (-0.59;41.02)	1.3 (0.98; 1.81)	2.8 (0.91; 8.58)	0.0700	
Placebo + TCS	36	22 (61.1)					
Using RDCSA							
Tralokinumab Q2W + TCS	103	79 (76.7)	18.5 (5.79;31.24)	1.3 (1.08; 1.61)	2.4 (1.29; 4.35)	0.0052	
Placebo + TCS	98	57 (58.2)					

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 Prior CSA use and baseline IGA. Including subjects with a baseline score of at least 4.

17FEB21 16:55 LP0162-Payer /p_bin_eff1/T_t_csa_f33_46_w16.txt

Table 1.17.335.4.1: Total, RDSCA Use, DLQI 0/1, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	32 (23.2)	6.9 (-2.56;16.32)	1.4 (0.87; 2.35)	1.5 (0.85; 2.81)	0.1545	0.0138
Placebo + TCS	136	22 (16.2)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	3 (9.1)	-13.2 (-29.9; 3.48)	0.4 (0.12; 1.40)	0.3 (0.08; 1.45)	0.1393	
Placebo + TCS	36	8 (22.2)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	29 (27.6)	13.6 (2.68;24.57)	2.0 (1.11; 3.51)	2.3 (1.15; 4.74)	0.0171	
Placebo + TCS	100	14 (14.0)					

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 Prior CSA use and baseline IGA.

17FEB21 17:03 LP0162-Payer /p_bin_eff1/T_t_csa_f35_46_w16.txt

Table 1.17.355.4.1: Total, RDSCA Use, EASI 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	96 (69.6)	16.8 (5.65;27.89)	1.3 (1.09; 1.59)	2.1 (1.27; 3.49)	0.0039	0.8308
Placebo + TCS	137	73 (53.3)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	26 (78.8)	12.4 (-7.47;32.25)	1.2 (0.90; 1.57)	2.0 (0.64; 6.25)	0.2363	
Placebo + TCS	36	24 (66.7)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	70 (66.7)	18.2 (4.98;31.50)	1.4 (1.08; 1.75)	2.1 (1.21; 3.75)	0.0083	
Placebo + TCS	101	49 (48.5)					

Treatment policy estimand: Missing values at Week 26 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.

17FEB21 17:09 LP0162-Payer /p_bin_eff1/T_t_csa_f55_46_w26.txt

Table 1.17.356.4.1: Total, RDSCA Use, EASI 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	67 (48.6)	14.1 (2.87;25.40)	1.4 (1.06; 1.86)	1.8 (1.12; 3.04)	0.0160	0.9264
Placebo + TCS	137	48 (35.0)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	21 (63.6)	13.8 (-8.78;36.48)	1.3 (0.85; 1.92)	1.8 (0.67; 4.87)	0.2432	
Placebo + TCS	36	18 (50.0)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	46 (43.8)	14.2 (1.24;27.21)	1.5 (1.02; 2.14)	1.9 (1.04; 3.31)	0.0350	
Placebo + TCS	101	30 (29.7)					

Treatment policy estimand: Missing values at Week 26 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.

17FEB21 17:06 LP0162-Payer /p_bin_eff1/T_t_csa_f56_46_w26.txt

Table 1.17.359.4.1: Total, RDSCA Use, SCORAD 75, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	53 (38.4)	20.6 (10.39;30.82)	2.1 (1.42; 3.22)	3.0 (1.68; 5.21)	0.0001	0.4084
Placebo + TCS	137	25 (18.2)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	17 (51.5)	18.2 (-4.92;41.41)	1.5 (0.87; 2.74)	2.1 (0.80; 5.52)	0.1300	
Placebo + TCS	36	12 (33.3)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	36 (34.3)	21.4 (10.18;32.60)	2.7 (1.50; 4.70)	3.5 (1.73; 7.11)	0.0003	
Placebo + TCS	101	13 (12.9)					

Treatment policy estimand: Missing values at Week 26 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.

17FEB21 16:53 LP0162-Payer /p_bin_eff1/T_t_csa_f59_46_w26.txt

Table 1.17.360.4.1: Total, RDSCA Use, Worst weekly pruritus NRS improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	134	64 (47.8)	8.3 (-3.43;20.09)	1.2 (0.92; 1.60)	1.4 (0.87; 2.29)	0.1650	0.0879
Placebo + TCS	135	53 (39.3)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	13 (39.4)	-8.5 (-31.5;14.48)	0.8 (0.48; 1.40)	0.7 (0.26; 1.86)	0.4712	
Placebo + TCS	35	17 (48.6)					
Using RDCSA							
Tralokinumab Q2W + TCS	101	51 (50.5)	14.0 (0.52;27.53)	1.4 (1.00; 1.92)	1.8 (1.01; 3.16)	0.0438	
Placebo + TCS	100	36 (36.0)					

Treatment policy estimand: Missing values at Week 26 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.

17FEB21 17:08 LP0162-Payer /p_bin_eff1/T_t_csa_f60_46_w26.txt

Table 1.17.361.4.1: Total, RDSCA Use, Worst weekly pruritus NRS improvement of >= 3, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	137	86 (62.8)	16.0 (4.45;27.60)	1.3 (1.08; 1.67)	1.9 (1.19; 3.16)	0.0078	0.4939
Placebo + TCS	136	64 (47.1)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	22 (66.7)	8.5 (-13.8;30.90)	1.1 (0.80; 1.65)	1.5 (0.54; 3.96)	0.4627	
Placebo + TCS	36	21 (58.3)					
Using RDCSA							
Tralokinumab Q2W + TCS	104	64 (61.5)	18.6 (5.08;32.04)	1.4 (1.09; 1.88)	2.1 (1.21; 3.71)	0.0083	
Placebo + TCS	100	43 (43.0)					

Treatment policy estimand: Missing values at Week 26 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.

17FEB21 16:59 LP0162-Payer /p_bin_eff1/T_t_csa_f61_46_w26.txt

Table 1.17.363.4.1: Total, RDSCA Use, POEM improvement of >= 4, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	135	105 (77.8)	21.3 (10.39;32.18)	1.4 (1.16; 1.64)	2.7 (1.59; 4.63)	0.0002	0.8392
Placebo + TCS	134	76 (56.7)					
Not using RDCSA							
Tralokinumab Q2W + TCS	32	26 (81.3)	17.3 (-3.33;37.92)	1.3 (0.95; 1.71)	2.5 (0.80; 7.57)	0.1160	
Placebo + TCS	36	23 (63.9)					
Using RDCSA							
Tralokinumab Q2W + TCS	103	79 (76.7)	22.6 (9.83;35.43)	1.4 (1.15; 1.75)	2.8 (1.53; 5.13)	0.0008	
Placebo + TCS	98	53 (54.1)					

Treatment policy estimand: Missing values at Week 26 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.

17FEB21 17:09 LP0162-Payer /p_bin_eff1/T_t_csa_f63_46_w26.txt

Table 1.17.365.4.1: Total, RDSCA Use, DLQI 0/1, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	36 (26.1)	13.7 (4.62;22.81)	2.1 (1.25; 3.56)	2.5 (1.34; 4.85)	0.0038	0.2564
Placebo + TCS	136	17 (12.5)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	7 (21.2)	4.8 (-13.0;22.53)	1.3 (0.50; 3.30)	1.4 (0.40; 4.97)	0.6021	
Placebo + TCS	36	6 (16.7)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	29 (27.6)	16.7 (6.22;27.22)	2.5 (1.34; 4.76)	3.1 (1.46; 6.69)	0.0026	
Placebo + TCS	100	11 (11.0)					

Treatment policy estimand: Missing values at Week 26 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.

17FEB21 16:56 LP0162-Payer /p_bin_eff1/T_t_csa_f65_46_w26.txt

Table 1.17.385.4.1: Total, RDSCA Use, SCORAD 90, Treatment policy estimand, LP0162-1346, 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 Q2W + TCS	138	13 (9.4)	4.5 (-1.61;10.59)	1.9 (0.78; 4.54)	2.0 (0.77; 5.17)	0.1522	0.7275
Placebo + TCS	137	7 (5.1)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	6 (18.2)	9.9 (-6.12;25.82)	2.2 (0.59; 8.08)	2.4 (0.56;10.68)	0.2317	
Placebo + TCS	36	3 (8.3)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	7 (6.7)	2.7 (-3.44; 8.83)	1.7 (0.51; 5.52)	1.7 (0.49; 6.02)	0.3921	
Placebo + TCS	101	4 (4.0)					

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. Treatment policy estimand: Missing values at Week 16 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

17FEB21 16:56 LP0162-Payer /p_bin_eff2/T_t_csa_f85_46_w16.txt

Table 1.17.389.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)							
Total							
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)		
Week 16		123 4.2 (2.30)			124 3.3 (2.05)		
Week 16 chg		122 -3.3 (2.36)	-3.21 (0.19)		123 -3.9 (2.06)	-3.98 (0.19)	-0.77 (-1.30, -0.24) 0.004 [-0.35 (-0.60, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3089
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.389.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 7.4 (1.48)		33	33 7.0 (1.33)		
Week 16		32 3.8 (1.95)			32 3.3 (1.97)		
Week 16 chg		32 -3.5 (2.15)	-3.42 (0.34)		32 -3.7 (2.02)	-3.78 (0.34)	-0.37 (-1.33, 0.60) 0.452 [-0.18 (-0.67, 0.32)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3089
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.389.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	100 7.5 (1.34)		105	104 7.3 (1.49)			
Week 16		91 4.4 (2.40)			92 3.4 (2.08)			
Week 16 chg		90 -3.2 (2.43)	-3.13 (0.23)		91 -4.0 (2.08)	-4.06 (0.23)	-0.92 (-1.56, -0.29) [-0.41 (-0.70, -0.11)]	0.005

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3089
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.390.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 16		123 3.2 (2.41)			124 2.4 (2.16)		
Week 16 chg		122 -3.7 (2.29)	-3.50 (0.19)		123 -3.9 (2.32)	-4.03 (0.19)	-0.53 (-1.07, 0.01) 0.052 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7999
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.390.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 6.8 (1.73)		33	33 6.1 (2.06)			
Week 16		32 2.9 (2.18)			32 2.1 (1.99)			
Week 16 chg		32 -3.8 (2.16)	-3.65 (0.35)		32 -3.9 (2.33)	-4.10 (0.35)	-0.44 (-1.44, 0.55) [-0.20 (-0.69, 0.29)]	0.378

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7999
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.390.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA												
Baseline	101	100	7.0 (1.62)			105	104	6.4 (2.13)				
Week 16		91	3.4 (2.48)				92	2.5 (2.22)				
Week 16 chg		90	-3.6 (2.35)	-3.46	(0.23)		91	-3.9 (2.32)	-4.01	(0.23)	-0.56 (-1.20, 0.08) [-0.24 (-0.53, 0.05)]	0.087

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7999
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.391.4.1: Total, RDSCA Use, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
SCORAD Score								
Total								
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)			
Week 16		124 36.3 (18.78)			123 27.0 (16.90)			
Week 16 chg		124 -34.7 (19.94)	-34.36 (1.54)		123 -43.3 (19.46)	-43.61 (1.55)	-9.25 (-13.6, -4.94) [-0.47 (-0.72, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4616
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.391.4.1: Total, RDSCA Use, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 70.1 (12.80)		33	33 68.7 (10.87)			
Week 16		32 28.2 (17.44)			31 21.6 (16.73)			
Week 16 chg		32 -42.1 (20.52)	-41.81 (2.99)		31 -47.9 (19.66)	-48.69 (3.04)	-6.87 (-15.4, 1.65) [-0.34 (-0.84, 0.16)]	0.112

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4616
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.391.4.1: Total, RDSCA Use, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	101 71.1 (12.91)		105	105 70.7 (12.40)			
Week 16		92 39.1 (18.49)			92 28.8 (16.65)			
Week 16 chg		92 -32.1 (19.18)	-31.88 (1.79)		92 -41.7 (19.24)	-41.97 (1.80)	-10.09 (-15.1, -5.08) [-0.53 (-0.82, -0.23)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4616
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.392.4.1: Total, RDSCA Use, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 16		122 6.4 (5.60)			119 4.5 (3.87)		
Week 16 chg		120 -10.0 (6.54)	-9.61 (0.40)		118 -11.0 (5.99)	-11.29 (0.41)	-1.68 (-2.82, -0.55) 0.004 [-0.27 (-0.52, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0090
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.392.4.1: Total, RDSCA Use, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 15.8 (5.16)		33	33 15.7 (5.32)			
Week 16		31 4.7 (3.38)			30 5.5 (3.56)			
Week 16 chg		31 -11.2 (5.22)	-11.22 (0.58)		30 -10.3 (5.13)	-10.40 (0.59)	0.83 (-0.83, 2.48) [0.16 (-0.34, 0.66)]	0.321

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0090
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.392.4.1: Total, RDSCA Use, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA										
Baseline	101	98	16.6 (6.72)		105	104	15.9 (6.89)			
Week 16		91	7.0 (6.07)			89	4.1 (3.92)			
Week 16 chg		89	-9.5 (6.92)	-9.07 (0.50)		88	-11.2 (6.27)	-11.60 (0.50)	-2.54 (-3.93, -1.14) [-0.38 (-0.68, -0.09)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0090
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.393.4.1: Total, RDSCA Use, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total							
Total							
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)		
Week 16		122 12.9 (7.67)			119 9.0 (5.53)		
Week 16 chg		120 -8.0 (8.09)	-8.10 (0.59)		116 -12.2 (6.39)	-12.12 (0.60)	-4.02 (-5.68, -2.36) <.001 [-0.55 (-0.81, -0.29)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2050
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.393.4.1: Total, RDSCA Use, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 19.9 (5.44)		33	32 21.5 (4.80)			
Week 16		31 11.3 (7.56)			30 9.8 (5.71)			
Week 16 chg		31 -8.5 (8.08)	-9.22 (1.21)		29 -12.0 (6.32)	-11.34 (1.24)	-2.12 (-5.62, 1.38) [-0.29 (-0.80, 0.22)]	0.230

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2050
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.393.4.1: Total, RDSCA Use, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	98 21.2 (5.81)		105	103 21.2 (5.24)			
Week 16		91 13.4 (7.67)			89 8.7 (5.47)			
Week 16 chg		89 -7.8 (8.14)	-7.73 (0.68)		87 -12.3 (6.45)	-12.37 (0.69)	-4.64 (-6.55, -2.72) [-0.63 (-0.93, -0.33)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2050
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.395.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 16		122	69.3 (21.69)			119	75.7 (16.92)		
Week 16 chg		120	16.7 (26.74)	14.64 (1.75)		116	17.7 (22.49)	19.84 (1.78)	5.21 (0.28, 10.14) 0.039 [0.21 (-0.05, 0.47)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9554
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.395.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 52.8 (21.28)		33	32 57.4 (18.26)		
Week 16		31 66.7 (24.94)			30 72.7 (19.71)		
Week 16 chg		31 14.0 (32.98)	12.38 (4.08)		29 16.4 (20.60)	17.89 (4.23)	5.51 (-6.26, 17.28) 0.352 [0.20 (-0.31, 0.71)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9554
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.395.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA										
Baseline	101	98	52.4 (22.33)		105	103	56.3 (20.46)			
Week 16		91	70.2 (20.55)			89	76.8 (15.87)			
Week 16 chg		89	17.6 (24.35)	15.36 (1.90)		87	18.1 (23.18)	20.45 (1.92)	5.09 (-0.27, 10.46) [0.21 (-0.08, 0.51)]	0.063

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9554
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.396.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 16		124 2.7 (2.77)			123 1.9 (2.39)		
Week 16 chg		124 -4.1 (3.25)	-3.99 (0.23)		123 -4.7 (2.92)	-4.72 (0.23)	-0.73 (-1.36, -0.09) 0.025 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1661
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.396.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 6.7 (2.09)		33	33 6.6 (2.01)			
Week 16		32 1.9 (2.08)			31 1.9 (2.43)			
Week 16 chg		32 -4.8 (2.70)	-4.84 (0.40)		31 -4.8 (2.80)	-4.79 (0.41)	0.04 (-1.10, 1.18) [0.02 (-0.48, 0.51)]	0.941

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1661
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.396.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	101 6.8 (2.26)		105	105 6.7 (2.47)			
Week 16		92 3.0 (2.93)			92 2.0 (2.39)			
Week 16 chg		92 -3.8 (3.40)	-3.71 (0.27)		92 -4.6 (2.98)	-4.69 (0.27)	-0.99 (-1.75, -0.22) [-0.31 (-0.60, -0.02)]	0.012

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1661
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.398.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 26		115	72.6 (20.73)			119	76.4 (17.30)		
Week 26 chg		113	20.5 (25.83)	18.74 (1.72)		116	19.5 (21.18)	21.31 (1.70)	2.56 (-2.22, 7.35) 0.292 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1914
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.398.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 52.8 (21.28)		33	32 57.4 (18.26)			
Week 26		32 69.8 (21.64)			28 76.8 (14.43)			
Week 26 chg		32 17.0 (29.64)	16.29 (3.17)		27 23.7 (18.60)	24.58 (3.45)	8.29 (-1.11, 17.69) [0.33 (-0.19, 0.84)]	0.083

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1914
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.398.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA									
Baseline	101	98	52.4 (22.33)		105	103	56.3 (20.46)		
Week 26		83	73.7 (20.39)			91	76.3 (18.16)		
Week 26 chg		81	21.9 (24.23)	19.78 (2.03)		89	18.2 (21.83)	20.16 (1.93)	0.39 (-5.17, 5.94) 0.891 [0.02 (-0.28, 0.32)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1914
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.401.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.56 (0.82)		138 -12.9 (10.72)	-13.28 (0.82)	-0.72 (-3.02, 1.57) 0.536 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.48 (0.83)		137 -18.8 (10.58)	-19.37 (0.82)	-1.88 (-4.18, 0.42) 0.109 [-0.17 (-0.41, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.42 (0.83)		134 -20.9 (11.93)	-21.43 (0.83)	-3.01 (-5.32, -0.70) 0.011 [-0.25 (-0.49, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.19 (0.83)		130 -22.5 (12.16)	-23.11 (0.83)	-3.92 (-6.23, -1.60) <.001 [-0.30 (-0.54, -0.06)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.50 (0.83)		130 -24.3 (11.55)	-24.96 (0.83)	-4.46 (-6.78, -2.14) <.001 [-0.35 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-20.99 (0.84)		128 -24.7 (12.40)	-25.11 (0.84)	-4.13 (-6.46, -1.80) <.001 [-0.31 (-0.56, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8539
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.401.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 11.2 (11.57)			127 7.0 (8.34)		
Week 14 chg		126 -22.8 (14.69)	-21.74 (0.84)		127 -25.1 (13.29)	-25.62 (0.84)	-3.87 (-6.21, -1.54) 0.001 [-0.28 (-0.52, -0.03)]
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.54 (0.84)		123 -25.9 (12.78)	-26.06 (0.84)	-3.52 (-5.86, -1.17) 0.003 [-0.25 (-0.50, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8539
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.401.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 31.9 (13.21)		33	33 30.2 (8.24)		
Week 2		36 19.1 (11.62)			33 15.4 (11.55)		
Week 2 chg		36 -12.8 (10.52)	-12.49 (1.49)		33 -14.8 (10.18)	-15.26 (1.55)	-2.78 (-7.04, 1.48) 0.200 [-0.27 (-0.74, 0.21)]
Week 4		35 12.9 (11.75)			33 11.0 (9.62)		
Week 4 chg		35 -19.3 (12.20)	-18.74 (1.50)		33 -19.2 (10.44)	-19.80 (1.55)	-1.07 (-5.35, 3.21) 0.623 [-0.09 (-0.57, 0.38)]
Week 6		34 12.0 (11.18)			33 8.8 (9.50)		
Week 6 chg		34 -20.6 (13.43)	-19.47 (1.51)		33 -21.3 (11.29)	-22.13 (1.55)	-2.66 (-6.96, 1.64) 0.223 [-0.21 (-0.69, 0.27)]
Week 8		35 10.8 (11.41)			33 7.3 (8.24)		
Week 8 chg		35 -21.5 (13.66)	-20.71 (1.50)		33 -22.8 (10.73)	-23.64 (1.55)	-2.93 (-7.21, 1.35) 0.178 [-0.24 (-0.71, 0.24)]
Week 10		35 9.1 (9.07)			33 4.7 (5.20)		
Week 10 chg		35 -23.1 (12.32)	-22.29 (1.50)		33 -25.5 (9.61)	-26.37 (1.55)	-4.08 (-8.36, 0.20) 0.061 [-0.37 (-0.85, 0.11)]
Week 12		34 8.8 (8.90)			33 5.6 (7.66)		
Week 12 chg		34 -23.6 (11.81)	-22.45 (1.51)		33 -24.6 (10.89)	-25.41 (1.55)	-2.97 (-7.26, 1.33) 0.174 [-0.26 (-0.74, 0.22)]
Week 14		33 8.6 (9.88)			33 4.8 (8.07)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8539
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.401.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	33	-23.4 (13.18)	-22.08 (1.52)	33	-25.4 (11.29)	-26.24 (1.55)	-4.16 (-8.46, 0.15) 0.058 [-0.34 (-0.82, 0.15)]
Week 16	32	7.2 (9.39)		31	4.2 (7.25)		
Week 16 chg	32	-25.0 (12.94)	-23.14 (1.53)	31	-26.2 (11.01)	-27.03 (1.58)	-3.89 (-8.24, 0.46) 0.079 [-0.32 (-0.82, 0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8539
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.401.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA							
Baseline	101	101 34.5 (13.55)		105	105 32.7 (12.35)		
Week 2		101 21.6 (14.67)			105 20.4 (12.92)		
Week 2 chg		101 -12.9 (11.43)	-12.62 (0.99)		105 -12.3 (10.86)	-12.64 (0.97)	-0.02 (-2.75, 2.71) 0.990 [-0.00 (-0.27, 0.27)]
Week 4		99 16.6 (12.78)			104 13.8 (10.56)		
Week 4 chg		99 -17.8 (11.87)	-17.07 (0.99)		104 -18.7 (10.67)	-19.22 (0.97)	-2.15 (-4.89, 0.59) 0.124 [-0.19 (-0.47, 0.09)]
Week 6		98 15.7 (12.72)			101 12.0 (9.65)		
Week 6 chg		98 -18.8 (12.36)	-18.06 (1.00)		101 -20.8 (12.18)	-21.22 (0.98)	-3.16 (-5.91, -0.41) 0.025 [-0.26 (-0.54, 0.02)]
Week 8		98 15.2 (13.03)			97 10.4 (8.48)		
Week 8 chg		98 -19.3 (13.94)	-18.68 (1.00)		97 -22.4 (12.67)	-22.95 (0.99)	-4.26 (-7.03, -1.50) 0.003 [-0.32 (-0.60, -0.04)]
Week 10		96 13.7 (12.29)			97 8.7 (7.82)		
Week 10 chg		96 -20.9 (14.49)	-19.88 (1.00)		97 -23.8 (12.15)	-24.50 (0.99)	-4.63 (-7.40, -1.86) 0.001 [-0.35 (-0.63, -0.06)]
Week 12		94 13.2 (11.76)			95 8.3 (7.82)		
Week 12 chg		94 -21.7 (15.08)	-20.49 (1.00)		95 -24.8 (12.93)	-25.01 (0.99)	-4.52 (-7.30, -1.74) 0.001 [-0.32 (-0.61, -0.03)]
Week 14		93 12.2 (12.02)			94 7.8 (8.34)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8539
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.401.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	93	-22.6 (15.26)	-21.65 (1.01)	94	-25.0 (13.97)	-25.40 (0.99)	-3.75 (-6.54, -0.97) 0.008 [-0.26 (-0.54, 0.03)]
Week 16	92	11.7 (11.87)		92	7.1 (7.65)		
Week 16 chg	92	-23.3 (15.61)	-22.36 (1.01)	92	-25.7 (13.37)	-25.74 (1.00)	-3.38 (-6.17, -0.58) 0.018 [-0.23 (-0.52, 0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8539
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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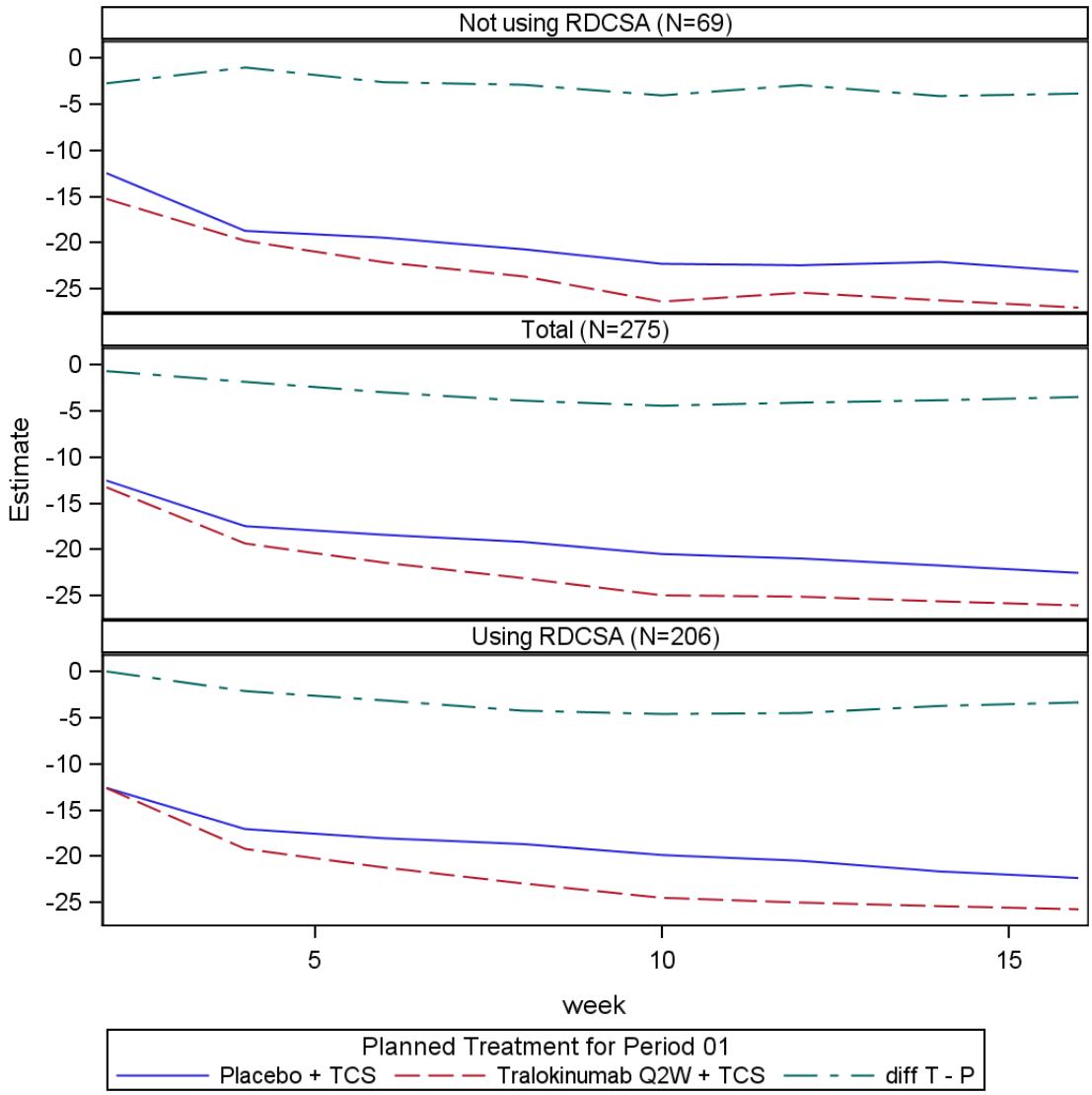
Figure 1.17.401.4.2: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 16



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 Prior CSA use, 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 1.17.403.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)									
Total									
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)		
Week 1		135	6.3 (1.69)			136	6.0 (1.78)		
Week 1 chg		135	-1.1 (1.34)	-1.14 (0.17)		136	-1.2 (1.31)	-1.23 (0.17)	-0.08 (-0.56, 0.39) 0.732 [-0.06 (-0.30, 0.18)]
Week 2		134	5.8 (1.97)			132	5.4 (2.11)		
Week 2 chg		134	-1.7 (1.78)	-1.67 (0.17)		132	-1.9 (1.67)	-1.92 (0.17)	-0.24 (-0.72, 0.24) 0.324 [-0.14 (-0.38, 0.10)]
Week 3		133	5.3 (2.17)			131	4.8 (2.08)		
Week 3 chg		133	-2.2 (2.12)	-2.11 (0.17)		131	-2.5 (1.84)	-2.53 (0.17)	-0.42 (-0.90, 0.06) 0.088 [-0.21 (-0.45, 0.03)]
Week 4		130	5.1 (2.25)			133	4.4 (2.14)		
Week 4 chg		130	-2.4 (2.14)	-2.29 (0.17)		133	-2.8 (1.92)	-2.87 (0.17)	-0.58 (-1.06, -0.10) 0.019 [-0.28 (-0.53, -0.04)]
Week 5		131	4.9 (2.37)			129	4.2 (2.15)		
Week 5 chg		131	-2.6 (2.26)	-2.54 (0.17)		129	-3.1 (1.92)	-3.16 (0.17)	-0.62 (-1.10, -0.14) 0.012 [-0.30 (-0.54, -0.05)]
Week 6		130	4.8 (2.35)			129	4.2 (2.16)		
Week 6 chg		130	-2.7 (2.25)	-2.58 (0.17)		129	-3.1 (1.99)	-3.14 (0.17)	-0.57 (-1.05, -0.08) 0.021 [-0.27 (-0.51, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7799
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 12:09 LP0162-Payer /p_mmrm3/t_t_csa_g03_46_w16.txt

Table 1.17.403.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	4.7 (2.24)		128	4.0 (2.13)			
Week 7 chg	129	-2.8 (2.25)	-2.73 (0.17)	128	-3.3 (2.05)	-3.38 (0.17)	-0.65 (-1.13, -0.16) [-0.30 (-0.55, -0.05)]	0.009
Week 8	127	4.7 (2.32)		125	3.7 (2.10)			
Week 8 chg	127	-2.8 (2.27)	-2.73 (0.17)	125	-3.7 (1.96)	-3.64 (0.17)	-0.92 (-1.40, -0.43) [-0.43 (-0.68, -0.18)]	<.001
Week 9	127	4.6 (2.37)		127	3.6 (2.10)			
Week 9 chg	127	-2.9 (2.32)	-2.79 (0.17)	127	-3.7 (2.03)	-3.71 (0.17)	-0.92 (-1.40, -0.44) [-0.42 (-0.67, -0.17)]	<.001
Week 10	125	4.5 (2.42)		122	3.6 (2.11)			
Week 10 chg	125	-2.9 (2.39)	-2.87 (0.17)	122	-3.7 (1.93)	-3.70 (0.17)	-0.83 (-1.32, -0.35) [-0.38 (-0.63, -0.13)]	<.001
Week 11	128	4.4 (2.41)		126	3.5 (2.15)			
Week 11 chg	128	-3.1 (2.40)	-3.06 (0.17)	126	-3.7 (1.97)	-3.75 (0.17)	-0.70 (-1.18, -0.21) [-0.32 (-0.56, -0.07)]	0.005
Week 12	123	4.4 (2.36)		121	3.5 (2.08)			
Week 12 chg	123	-3.1 (2.41)	-3.03 (0.17)	121	-3.8 (2.06)	-3.82 (0.17)	-0.80 (-1.28, -0.31) [-0.35 (-0.61, -0.10)]	0.001
Week 13	116	4.3 (2.38)		120	3.3 (2.06)			
Week 13 chg	116	-3.3 (2.35)	-3.09 (0.18)	120	-4.0 (2.09)	-3.92 (0.17)	-0.84 (-1.32, -0.35) [-0.38 (-0.63, -0.12)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7799
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 12:09 LP0162-Payer /p_mmrm3/t_t_csa_g03_46_w16.txt

Table 1.17.403.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.13 (0.17)	123	-3.9 (2.12)	-3.85 (0.17)	-0.72 (-1.20, -0.23) [-0.32 (-0.57, -0.07)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.16 (0.17)	123	-4.0 (2.15)	-3.93 (0.17)	-0.76 (-1.25, -0.28) [-0.34 (-0.59, -0.09)]	0.002
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.10 (0.17)	122	-3.9 (2.06)	-3.93 (0.17)	-0.83 (-1.32, -0.35) [-0.38 (-0.63, -0.12)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7799
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 12:09 LP0162-Payer /p_mmrm3/t_t_csa_g03_46_w16.txt

Table 1.17.403.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 7.4 (1.48)		33	33 7.0 (1.33)			
Week 1		35 5.8 (1.77)			33 6.0 (1.76)			
Week 1 chg		35 -1.5 (1.54)	-1.49 (0.33)		33 -1.1 (1.21)	-1.09 (0.34)	0.40 (-0.54, 1.34) [0.29 (-0.19, 0.77)]	0.397
Week 2		36 5.4 (1.91)			32 5.3 (1.92)			
Week 2 chg		36 -2.0 (1.70)	-1.92 (0.33)		32 -1.7 (1.46)	-1.75 (0.34)	0.17 (-0.77, 1.11) [0.11 (-0.37, 0.58)]	0.721
Week 3		35 4.7 (1.89)			31 4.9 (2.03)			
Week 3 chg		35 -2.7 (2.00)	-2.52 (0.33)		31 -2.1 (1.66)	-2.16 (0.34)	0.36 (-0.59, 1.30) [0.19 (-0.29, 0.68)]	0.457
Week 4		34 4.7 (2.08)			32 4.5 (2.10)			
Week 4 chg		34 -2.6 (2.21)	-2.41 (0.33)		32 -2.5 (1.70)	-2.58 (0.34)	-0.17 (-1.12, 0.77) [-0.09 (-0.57, 0.39)]	0.715
Week 5		35 4.6 (2.26)			33 4.2 (2.02)			
Week 5 chg		35 -2.8 (2.33)	-2.68 (0.33)		33 -2.9 (1.74)	-2.93 (0.34)	-0.25 (-1.19, 0.69) [-0.12 (-0.60, 0.35)]	0.597
Week 6		34 4.5 (2.39)			32 4.2 (2.19)			
Week 6 chg		34 -2.8 (2.38)	-2.69 (0.33)		32 -2.8 (1.96)	-2.89 (0.34)	-0.20 (-1.15, 0.74) [-0.09 (-0.58, 0.39)]	0.672
Week 7		34 4.2 (2.19)			32 4.2 (2.17)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7799
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.403.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	34	-3.2 (2.39)	-3.01 (0.33)	32	-2.8 (2.03)	-2.92 (0.34)	0.09 (-0.85, 1.04) 0.847 [0.04 (-0.44, 0.52)]
Week 8	32	4.1 (2.28)		31	3.7 (2.25)		
Week 8 chg	32	-3.2 (2.35)	-3.10 (0.33)	31	-3.3 (1.92)	-3.32 (0.34)	-0.22 (-1.17, 0.73) 0.646 [-0.10 (-0.60, 0.39)]
Week 9	34	4.0 (2.18)		33	3.7 (2.22)		
Week 9 chg	34	-3.3 (2.30)	-3.18 (0.33)	33	-3.3 (2.02)	-3.40 (0.34)	-0.22 (-1.17, 0.72) 0.641 [-0.10 (-0.58, 0.38)]
Week 10	33	4.0 (2.15)		30	3.8 (2.20)		
Week 10 chg	33	-3.3 (2.29)	-3.30 (0.33)	30	-3.2 (1.94)	-3.29 (0.35)	0.01 (-0.95, 0.96) 0.990 [0.00 (-0.49, 0.50)]
Week 11	34	3.7 (2.02)		32	3.5 (2.31)		
Week 11 chg	34	-3.7 (2.15)	-3.55 (0.33)	32	-3.4 (2.01)	-3.56 (0.34)	-0.01 (-0.96, 0.94) 0.984 [-0.00 (-0.49, 0.48)]
Week 12	33	3.8 (2.16)		32	3.6 (2.14)		
Week 12 chg	33	-3.6 (2.21)	-3.43 (0.33)	32	-3.4 (1.90)	-3.53 (0.34)	-0.10 (-1.04, 0.85) 0.841 [-0.05 (-0.53, 0.44)]
Week 13	32	3.8 (1.98)		31	3.6 (2.18)		
Week 13 chg	32	-3.5 (2.08)	-3.48 (0.33)	31	-3.4 (2.01)	-3.49 (0.34)	-0.01 (-0.96, 0.94) 0.985 [-0.00 (-0.50, 0.49)]
Week 14	33	3.8 (1.98)		30	3.4 (2.26)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7799
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.403.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	33	-3.6 (1.93)	-3.49 (0.33)	30	-3.7 (1.89)	-3.61 (0.34)	-0.13 (-1.08, 0.82) [-0.07 (-0.56, 0.43)]	0.791
Week 15	33	3.8 (1.85)		31	3.2 (2.11)			
Week 15 chg	33	-3.6 (2.05)	-3.48 (0.33)	31	-3.8 (2.02)	-3.88 (0.34)	-0.40 (-1.35, 0.55) [-0.20 (-0.69, 0.29)]	0.404
Week 16	32	3.8 (1.95)		31	3.4 (1.97)			
Week 16 chg	32	-3.5 (2.15)	-3.44 (0.33)	31	-3.6 (2.03)	-3.83 (0.34)	-0.39 (-1.34, 0.56) [-0.19 (-0.68, 0.31)]	0.417

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7799
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 12:09 LP0162-Payer /p_mmrm3/t_t_csa_g03_46_w16.txt

Table 1.17.403.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA											
Baseline	101	100	7.5 (1.34)			105	104	7.3 (1.49)			
Week 1		100	6.5 (1.64)				103	6.1 (1.80)			
Week 1 chg		100	-1.0 (1.25)	-1.02	(0.20)		103	-1.3 (1.34)	-1.27	(0.20)	-0.25 (-0.81, 0.31) 0.380 [-0.19 (-0.47, 0.08)]
Week 2		98	5.9 (1.99)				100	5.4 (2.17)			
Week 2 chg		98	-1.6 (1.80)	-1.59	(0.20)		100	-2.0 (1.73)	-1.97	(0.20)	-0.38 (-0.94, 0.18) 0.185 [-0.21 (-0.49, 0.07)]
Week 3		98	5.5 (2.22)				100	4.7 (2.10)			
Week 3 chg		98	-2.0 (2.14)	-1.97	(0.20)		100	-2.6 (1.88)	-2.65	(0.20)	-0.68 (-1.24, -0.12) 0.018 [-0.34 (-0.62, -0.06)]
Week 4		96	5.3 (2.30)				101	4.4 (2.16)			
Week 4 chg		96	-2.3 (2.12)	-2.25	(0.20)		101	-2.9 (1.98)	-2.96	(0.20)	-0.71 (-1.27, -0.15) 0.014 [-0.34 (-0.63, -0.06)]
Week 5		96	5.0 (2.41)				96	4.2 (2.20)			
Week 5 chg		96	-2.6 (2.25)	-2.49	(0.20)		96	-3.2 (1.98)	-3.24	(0.20)	-0.75 (-1.31, -0.18) 0.009 [-0.35 (-0.64, -0.07)]
Week 6		96	4.9 (2.33)				97	4.2 (2.16)			
Week 6 chg		96	-2.6 (2.21)	-2.54	(0.20)		97	-3.2 (1.99)	-3.23	(0.20)	-0.69 (-1.25, -0.13) 0.017 [-0.33 (-0.61, -0.04)]
Week 7		95	4.8 (2.25)				96	3.9 (2.12)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7799
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.403.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	95	-2.7 (2.20)	-2.63 (0.20)	96	-3.5 (2.03)	-3.53 (0.20)	-0.90 (-1.46, -0.34) [-0.43 (-0.71, -0.14)]	0.002
Week 8	95	4.9 (2.31)		94	3.6 (2.06)			
Week 8 chg	95	-2.7 (2.23)	-2.60 (0.20)	94	-3.8 (1.96)	-3.75 (0.20)	-1.15 (-1.71, -0.59) [-0.55 (-0.84, -0.26)]	<.001
Week 9	93	4.9 (2.41)		94	3.6 (2.08)			
Week 9 chg	93	-2.7 (2.32)	-2.65 (0.20)	94	-3.8 (2.02)	-3.81 (0.20)	-1.16 (-1.72, -0.60) [-0.53 (-0.82, -0.24)]	<.001
Week 10	92	4.7 (2.49)		92	3.6 (2.09)			
Week 10 chg	92	-2.8 (2.42)	-2.72 (0.20)	92	-3.8 (1.92)	-3.84 (0.20)	-1.12 (-1.68, -0.55) [-0.51 (-0.81, -0.22)]	<.001
Week 11	94	4.6 (2.50)		94	3.6 (2.11)			
Week 11 chg	94	-2.9 (2.46)	-2.88 (0.20)	94	-3.8 (1.96)	-3.81 (0.20)	-0.93 (-1.49, -0.37) [-0.42 (-0.71, -0.13)]	0.001
Week 12	90	4.6 (2.41)		89	3.5 (2.07)			
Week 12 chg	90	-3.0 (2.47)	-2.89 (0.20)	89	-3.9 (2.11)	-3.91 (0.20)	-1.03 (-1.59, -0.46) [-0.45 (-0.74, -0.15)]	<.001
Week 13	84	4.5 (2.49)		89	3.2 (2.02)			
Week 13 chg	84	-3.1 (2.45)	-2.94 (0.21)	89	-4.2 (2.09)	-4.06 (0.20)	-1.12 (-1.69, -0.55) [-0.49 (-0.80, -0.19)]	<.001
Week 14	90	4.4 (2.51)		93	3.4 (2.10)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7799
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.403.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	90	-3.1 (2.47)	-3.01 (0.20)	93	-4.0 (2.19)	-3.92 (0.20)	-0.91 (-1.48, -0.35) [-0.39 (-0.68, -0.10)]	0.002
Week 15	90	4.4 (2.45)		92	3.4 (2.11)			
Week 15 chg	90	-3.2 (2.42)	-3.05 (0.20)	92	-4.0 (2.20)	-3.94 (0.20)	-0.89 (-1.46, -0.33) [-0.39 (-0.68, -0.09)]	0.002
Week 16	89	4.4 (2.39)		91	3.4 (2.09)			
Week 16 chg	89	-3.2 (2.42)	-2.98 (0.20)	91	-4.0 (2.08)	-3.97 (0.20)	-0.99 (-1.55, -0.42) [-0.44 (-0.73, -0.14)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7799
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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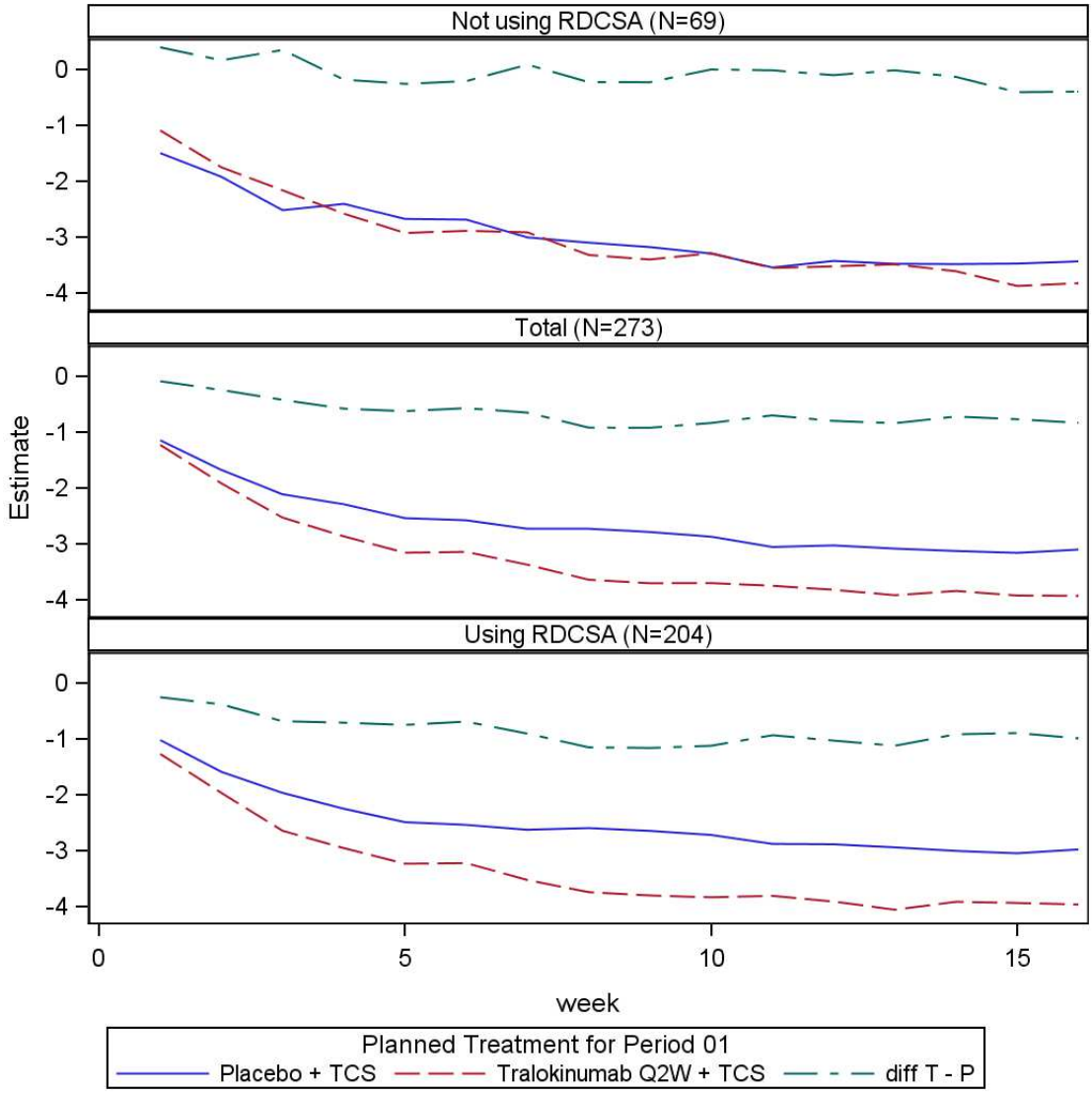
Figure 1.17.403.4.2: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 16



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 Prior CSA use, 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 1.17.405.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Interference With Sleep (eDiary)										
Total										
Baseline	137	136	6.9 (1.64)		138	137	6.3 (2.11)			
Week 1		135	5.8 (2.01)			136	5.2 (2.21)			
Week 1 chg		135	-1.1 (1.50)	-1.07 (0.18)		136	-1.1 (1.45)	-1.15 (0.18)	-0.08 (-0.58, 0.42) [-0.05 (-0.29, 0.18)]	0.756
Week 2		134	5.2 (2.29)			132	4.5 (2.45)			
Week 2 chg		134	-1.7 (1.98)	-1.67 (0.18)		132	-1.8 (1.80)	-1.85 (0.18)	-0.18 (-0.68, 0.33) [-0.09 (-0.33, 0.15)]	0.493
Week 3		133	4.7 (2.36)			131	3.9 (2.35)			
Week 3 chg		133	-2.2 (2.17)	-2.13 (0.18)		131	-2.4 (2.01)	-2.49 (0.18)	-0.36 (-0.86, 0.14) [-0.17 (-0.41, 0.07)]	0.160
Week 4		130	4.5 (2.48)			133	3.6 (2.39)			
Week 4 chg		130	-2.4 (2.23)	-2.26 (0.18)		133	-2.7 (2.06)	-2.79 (0.18)	-0.53 (-1.03, -0.03) [-0.25 (-0.49, -0.01)]	0.038
Week 5		131	4.2 (2.55)			129	3.3 (2.42)			
Week 5 chg		131	-2.7 (2.37)	-2.56 (0.18)		129	-3.0 (2.16)	-3.14 (0.18)	-0.58 (-1.08, -0.07) [-0.25 (-0.50, -0.01)]	0.024
Week 6		130	4.2 (2.52)			129	3.3 (2.42)			
Week 6 chg		130	-2.7 (2.36)	-2.53 (0.18)		129	-3.1 (2.24)	-3.20 (0.18)	-0.67 (-1.17, -0.17) [-0.29 (-0.54, -0.05)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.405.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	3.9 (2.43)		128	3.1 (2.37)			
Week 7 chg	129	-3.0 (2.38)	-2.81 (0.18)	128	-3.3 (2.28)	-3.41 (0.18)	-0.60 (-1.10, -0.10) [-0.26 (-0.50, -0.01)]	0.020
Week 8	127	3.9 (2.46)		125	2.8 (2.29)			
Week 8 chg	127	-3.0 (2.32)	-2.79 (0.18)	125	-3.6 (2.26)	-3.65 (0.18)	-0.86 (-1.36, -0.35) [-0.37 (-0.62, -0.12)]	<.001
Week 9	127	3.8 (2.49)		127	2.6 (2.22)			
Week 9 chg	127	-3.1 (2.33)	-2.92 (0.18)	127	-3.7 (2.23)	-3.83 (0.18)	-0.91 (-1.41, -0.40) [-0.40 (-0.65, -0.15)]	<.001
Week 10	125	3.7 (2.54)		122	2.7 (2.29)			
Week 10 chg	125	-3.2 (2.40)	-3.04 (0.18)	122	-3.7 (2.29)	-3.82 (0.18)	-0.79 (-1.29, -0.28) [-0.33 (-0.59, -0.08)]	0.002
Week 11	128	3.6 (2.46)		126	2.6 (2.22)			
Week 11 chg	128	-3.3 (2.40)	-3.15 (0.18)	126	-3.8 (2.26)	-3.89 (0.18)	-0.75 (-1.25, -0.24) [-0.32 (-0.57, -0.07)]	0.004
Week 12	123	3.5 (2.44)		121	2.5 (2.21)			
Week 12 chg	123	-3.4 (2.45)	-3.18 (0.18)	121	-3.8 (2.38)	-4.01 (0.18)	-0.82 (-1.33, -0.31) [-0.34 (-0.59, -0.09)]	0.002
Week 13	116	3.4 (2.40)		120	2.3 (2.13)			
Week 13 chg	116	-3.6 (2.32)	-3.32 (0.18)	120	-3.9 (2.26)	-4.05 (0.18)	-0.74 (-1.25, -0.23) [-0.32 (-0.58, -0.06)]	0.005

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.405.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	3.3 (2.42)		123	2.4 (2.18)			
Week 14 chg	123	-3.5 (2.33)	-3.36 (0.18)	123	-3.9 (2.27)	-4.03 (0.18)	-0.67 (-1.18, -0.16) [-0.29 (-0.54, -0.04)]	0.010
Week 15	123	3.3 (2.47)		123	2.4 (2.18)			
Week 15 chg	123	-3.7 (2.35)	-3.42 (0.18)	123	-3.9 (2.35)	-4.08 (0.18)	-0.66 (-1.16, -0.15) [-0.28 (-0.53, -0.03)]	0.011
Week 16	121	3.2 (2.40)		122	2.5 (2.17)			
Week 16 chg	121	-3.7 (2.28)	-3.41 (0.18)	122	-3.9 (2.32)	-4.06 (0.18)	-0.65 (-1.16, -0.14) [-0.28 (-0.54, -0.03)]	0.012

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.405.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 6.8 (1.73)		33	33 6.1 (2.06)			
Week 1		35 5.4 (2.09)			33 5.2 (2.16)			
Week 1 chg		35 -1.3 (1.44)	-1.27 (0.32)		33 -0.9 (1.45)	-0.91 (0.34)	0.36 (-0.58, 1.29) [0.25 (-0.23, 0.73)]	0.449
Week 2		36 4.9 (2.14)			32 4.5 (2.37)			
Week 2 chg		36 -1.8 (1.74)	-1.78 (0.32)		32 -1.6 (1.65)	-1.72 (0.34)	0.07 (-0.87, 1.00) [0.04 (-0.44, 0.51)]	0.890
Week 3		35 4.2 (2.00)			31 3.9 (2.42)			
Week 3 chg		35 -2.6 (1.85)	-2.43 (0.32)		31 -2.2 (1.77)	-2.33 (0.34)	0.11 (-0.83, 1.04) [0.06 (-0.43, 0.54)]	0.824
Week 4		34 4.1 (2.19)			32 3.6 (2.40)			
Week 4 chg		34 -2.5 (2.00)	-2.36 (0.33)		32 -2.4 (1.88)	-2.58 (0.34)	-0.21 (-1.15, 0.73) [-0.11 (-0.59, 0.37)]	0.657
Week 5		35 4.0 (2.39)			33 3.3 (2.38)			
Week 5 chg		35 -2.8 (2.13)	-2.60 (0.32)		33 -2.8 (2.01)	-2.91 (0.34)	-0.30 (-1.24, 0.63) [-0.15 (-0.62, 0.33)]	0.520
Week 6		34 4.0 (2.56)			32 3.1 (2.47)			
Week 6 chg		34 -2.7 (2.33)	-2.52 (0.33)		32 -3.0 (2.23)	-3.16 (0.34)	-0.64 (-1.58, 0.30) [-0.28 (-0.76, 0.21)]	0.181
Week 7		34 3.6 (2.20)			32 3.2 (2.42)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.405.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	34	-3.2 (2.22)	-2.93 (0.33)	32	-2.8 (2.26)	-3.07 (0.34)	-0.14 (-1.08, 0.80) 0.768 [-0.06 (-0.55, 0.42)]
Week 8	32	3.5 (2.28)		31	2.9 (2.36)		
Week 8 chg	32	-3.2 (2.16)	-2.97 (0.33)	31	-3.2 (2.07)	-3.31 (0.34)	-0.34 (-1.28, 0.60) 0.478 [-0.16 (-0.66, 0.33)]
Week 9	34	3.4 (2.26)		33	2.7 (2.30)		
Week 9 chg	34	-3.3 (2.19)	-3.12 (0.33)	33	-3.4 (2.16)	-3.50 (0.34)	-0.38 (-1.32, 0.55) 0.418 [-0.18 (-0.66, 0.30)]
Week 10	33	3.5 (2.15)		30	2.7 (2.36)		
Week 10 chg	33	-3.3 (2.08)	-3.15 (0.33)	30	-3.4 (2.24)	-3.61 (0.34)	-0.46 (-1.41, 0.48) 0.335 [-0.21 (-0.71, 0.28)]
Week 11	34	3.0 (1.95)		32	2.5 (2.30)		
Week 11 chg	34	-3.7 (1.97)	-3.49 (0.33)	32	-3.5 (2.30)	-3.75 (0.34)	-0.26 (-1.20, 0.67) 0.578 [-0.12 (-0.61, 0.36)]
Week 12	33	3.0 (2.09)		32	2.5 (2.21)		
Week 12 chg	33	-3.7 (2.02)	-3.50 (0.33)	32	-3.5 (2.25)	-3.76 (0.34)	-0.27 (-1.21, 0.67) 0.577 [-0.12 (-0.61, 0.36)]
Week 13	32	3.0 (1.98)		31	2.3 (2.13)		
Week 13 chg	32	-3.7 (1.90)	-3.60 (0.33)	31	-3.7 (2.15)	-3.90 (0.34)	-0.30 (-1.25, 0.64) 0.526 [-0.15 (-0.64, 0.34)]
Week 14	33	3.1 (1.96)		30	2.2 (2.23)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.405.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	33	-3.7 (1.84)	-3.58 (0.33)	30	-3.9 (2.12)	-3.95 (0.34)	-0.36 (-1.31, 0.58) 0.448 [-0.18 (-0.68, 0.31)]
Week 15	33	2.8 (2.00)		31	2.1 (2.09)		
Week 15 chg	33	-4.0 (2.05)	-3.79 (0.33)	31	-4.0 (2.36)	-4.23 (0.34)	-0.44 (-1.38, 0.51) 0.362 [-0.20 (-0.69, 0.29)]
Week 16	32	2.9 (2.18)		31	2.2 (1.99)		
Week 16 chg	32	-3.8 (2.16)	-3.71 (0.33)	31	-4.0 (2.36)	-4.19 (0.34)	-0.48 (-1.43, 0.46) 0.312 [-0.21 (-0.71, 0.28)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.405.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA										
Baseline	101	100	7.0 (1.62)		105	104	6.4 (2.13)			
Week 1		100	5.9 (1.98)			103	5.2 (2.24)			
Week 1 chg		100	-1.0 (1.52)	-1.00 (0.21)		103	-1.2 (1.45)	-1.22 (0.21)	-0.22 (-0.82, 0.37) [-0.15 (-0.43, 0.13)]	0.462
Week 2		98	5.3 (2.35)			100	4.6 (2.49)			
Week 2 chg		98	-1.7 (2.07)	-1.63 (0.21)		100	-1.8 (1.85)	-1.88 (0.21)	-0.25 (-0.85, 0.35) [-0.13 (-0.41, 0.15)]	0.408
Week 3		98	4.8 (2.46)			100	3.9 (2.34)			
Week 3 chg		98	-2.1 (2.27)	-2.02 (0.21)		100	-2.5 (2.08)	-2.54 (0.21)	-0.52 (-1.11, 0.08) [-0.24 (-0.52, 0.04)]	0.089
Week 4		96	4.6 (2.57)			101	3.6 (2.39)			
Week 4 chg		96	-2.4 (2.31)	-2.22 (0.22)		101	-2.8 (2.12)	-2.85 (0.21)	-0.63 (-1.23, -0.04) [-0.29 (-0.57, -0.01)]	0.038
Week 5		96	4.3 (2.61)			96	3.3 (2.45)			
Week 5 chg		96	-2.7 (2.46)	-2.55 (0.22)		96	-3.1 (2.22)	-3.21 (0.21)	-0.66 (-1.26, -0.06) [-0.28 (-0.57, 0.00)]	0.031
Week 6		96	4.3 (2.52)			97	3.3 (2.42)			
Week 6 chg		96	-2.7 (2.38)	-2.54 (0.22)		97	-3.1 (2.25)	-3.21 (0.21)	-0.68 (-1.27, -0.08) [-0.29 (-0.58, -0.01)]	0.027
Week 7		95	4.0 (2.51)			96	3.0 (2.36)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.405.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	95	-2.9 (2.45)	-2.76 (0.22)	96	-3.5 (2.27)	-3.52 (0.21)	-0.75 (-1.35, -0.15) [-0.32 (-0.60, -0.03)]	0.014
Week 8	95	4.1 (2.52)		94	2.8 (2.28)			
Week 8 chg	95	-2.9 (2.38)	-2.73 (0.22)	94	-3.7 (2.32)	-3.76 (0.21)	-1.03 (-1.63, -0.43) [-0.44 (-0.73, -0.15)]	<.001
Week 9	93	4.0 (2.56)		94	2.6 (2.20)			
Week 9 chg	93	-3.0 (2.39)	-2.86 (0.22)	94	-3.8 (2.26)	-3.94 (0.21)	-1.08 (-1.68, -0.48) [-0.47 (-0.76, -0.18)]	<.001
Week 10	92	3.8 (2.67)		92	2.7 (2.29)			
Week 10 chg	92	-3.2 (2.52)	-3.00 (0.22)	92	-3.8 (2.32)	-3.89 (0.21)	-0.89 (-1.49, -0.29) [-0.37 (-0.66, -0.08)]	0.004
Week 11	94	3.8 (2.60)		94	2.6 (2.20)			
Week 11 chg	94	-3.2 (2.52)	-3.02 (0.22)	94	-3.8 (2.25)	-3.94 (0.21)	-0.92 (-1.52, -0.32) [-0.38 (-0.67, -0.09)]	0.003
Week 12	90	3.7 (2.55)		89	2.5 (2.23)			
Week 12 chg	90	-3.3 (2.59)	-3.07 (0.22)	89	-3.9 (2.42)	-4.08 (0.21)	-1.01 (-1.61, -0.41) [-0.40 (-0.70, -0.11)]	0.001
Week 13	84	3.5 (2.54)		89	2.3 (2.14)			
Week 13 chg	84	-3.5 (2.47)	-3.21 (0.22)	89	-4.0 (2.31)	-4.10 (0.21)	-0.89 (-1.49, -0.28) [-0.37 (-0.67, -0.07)]	0.004
Week 14	90	3.5 (2.57)		93	2.4 (2.18)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.405.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	90	-3.5 (2.50)	-3.28 (0.22)	93	-3.9 (2.33)	-4.05 (0.21)	-0.78 (-1.38, -0.17) [-0.32 (-0.61, -0.03)]	0.012
Week 15	90	3.5 (2.61)		92	2.5 (2.21)			
Week 15 chg	90	-3.6 (2.46)	-3.29 (0.22)	92	-3.9 (2.36)	-4.03 (0.21)	-0.74 (-1.34, -0.14) [-0.31 (-0.60, -0.02)]	0.016
Week 16	89	3.4 (2.47)		91	2.5 (2.23)			
Week 16 chg	89	-3.6 (2.33)	-3.30 (0.22)	91	-3.9 (2.32)	-4.01 (0.21)	-0.71 (-1.31, -0.11) [-0.31 (-0.60, -0.01)]	0.021

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6152
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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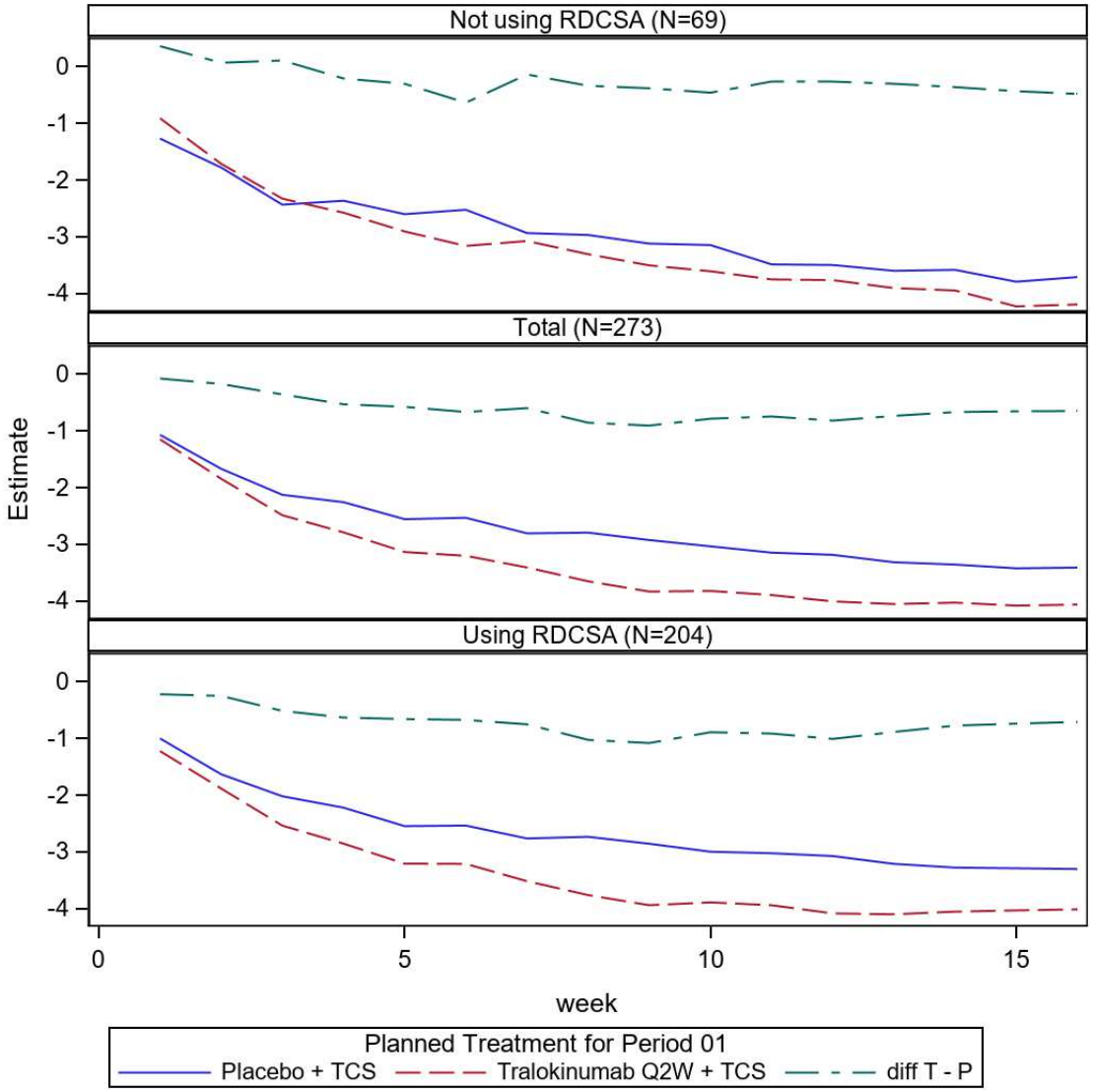
Figure 1.17.405.4.2: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 16



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 Prior CSA use, 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 1.17.407.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.22 (1.49)		138 -20.9 (16.72)	-21.06 (1.48)	-3.84 (-7.97, 0.30) 0.069 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.25 (1.50)		137 -30.8 (17.25)	-31.00 (1.49)	-4.75 (-8.90, -0.60) 0.025 [-0.27 (-0.51, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.77 (1.50)		134 -34.3 (17.49)	-34.45 (1.49)	-7.67 (-11.8, -3.51) <.001 [-0.42 (-0.66, -0.18)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.63 (1.50)		130 -36.6 (18.48)	-36.80 (1.50)	-8.16 (-12.3, -3.99) <.001 [-0.43 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.78 (1.50)		130 -38.5 (19.49)	-38.59 (1.50)	-7.81 (-12.0, -3.63) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.51 (1.51)		128 -39.5 (18.74)	-39.57 (1.51)	-8.06 (-12.3, -3.87) <.001 [-0.42 (-0.67, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1048
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.407.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	126	36.0 (19.61)		127	28.3 (17.87)		
Week 14 chg	126	-34.8 (20.31)	-34.13 (1.52)	127	-41.8 (20.11)	-41.35 (1.51)	-7.22 (-11.4, -3.01) <.001 [-0.36 (-0.61, -0.11)]
Week 16	124	36.3 (18.78)		123	27.0 (16.90)		
Week 16 chg	124	-34.7 (19.94)	-33.86 (1.52)	123	-43.3 (19.46)	-42.65 (1.52)	-8.79 (-13.0, -4.57) <.001 [-0.45 (-0.70, -0.19)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1048
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.407.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 70.1 (12.80)		33	33 68.7 (10.87)		
Week 2		36 52.8 (15.72)			33 43.1 (19.53)		
Week 2 chg		36 -17.3 (14.73)	-17.01 (3.03)		33 -25.6 (19.33)	-26.05 (3.17)	-9.04 (-17.7, -0.35) 0.042 [-0.53 (-1.01, -0.05)]
Week 4		35 41.4 (20.24)			33 36.9 (20.96)		
Week 4 chg		35 -28.9 (19.50)	-28.30 (3.06)		33 -31.8 (19.63)	-32.23 (3.17)	-3.93 (-12.7, 4.80) 0.375 [-0.20 (-0.68, 0.28)]
Week 6		34 42.5 (20.52)			33 28.6 (16.24)		
Week 6 chg		34 -28.3 (20.41)	-27.02 (3.08)		33 -40.0 (16.35)	-40.60 (3.17)	-13.58 (-22.3, -4.82) 0.003 [-0.73 (-1.23, -0.24)]
Week 8		35 37.6 (21.01)			33 28.2 (15.49)		
Week 8 chg		35 -32.7 (21.70)	-31.92 (3.06)		33 -40.4 (15.63)	-41.03 (3.17)	-9.12 (-17.8, -0.39) 0.041 [-0.48 (-0.96, 0.00)]
Week 10		35 34.8 (19.81)			33 25.2 (18.90)		
Week 10 chg		35 -35.5 (20.99)	-34.69 (3.06)		33 -43.5 (19.38)	-44.10 (3.17)	-9.41 (-18.1, -0.69) 0.035 [-0.47 (-0.95, 0.02)]
Week 12		34 34.2 (19.45)			33 26.9 (18.45)		
Week 12 chg		34 -36.3 (19.26)	-34.71 (3.07)		33 -41.8 (19.21)	-42.37 (3.17)	-7.66 (-16.4, 1.09) 0.086 [-0.40 (-0.88, 0.09)]
Week 14		33 32.0 (19.70)			33 23.3 (17.63)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1048
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.407.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	33	-37.7 (20.97)	-36.07 (3.09)	33	-45.4 (19.18)	-46.01 (3.17)	-9.94 (-18.7, -1.17) [-0.49 (-0.98, -0.00)]	0.027
Week 16	32	28.2 (17.44)		31	21.6 (16.73)			
Week 16 chg	32	-42.1 (20.52)	-39.06 (3.11)	31	-47.9 (19.66)	-48.64 (3.21)	-9.57 (-18.4, -0.73) [-0.48 (-0.98, 0.02)]	0.034

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1048
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.407.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA							
Baseline	101	101 71.1 (12.91)		105	105 70.7 (12.40)		
Week 2		101 53.6 (18.32)			105 51.3 (17.39)		
Week 2 chg		101 -17.5 (16.58)	-17.36 (1.72)		105 -19.4 (15.62)	-19.45 (1.68)	-2.08 (-6.81, 2.64) 0.386 [-0.13 (-0.40, 0.14)]
Week 4		99 44.7 (17.64)			104 39.9 (16.49)		
Week 4 chg		99 -26.1 (18.10)	-25.64 (1.72)		104 -30.5 (16.51)	-30.54 (1.69)	-4.90 (-9.64, -0.16) 0.043 [-0.28 (-0.56, -0.01)]
Week 6		98 43.7 (18.43)			101 38.1 (16.17)		
Week 6 chg		98 -27.1 (18.80)	-26.77 (1.73)		101 -32.4 (17.51)	-32.42 (1.70)	-5.65 (-10.4, -0.89) 0.020 [-0.31 (-0.59, -0.03)]
Week 8		98 43.0 (19.66)			97 35.1 (17.18)		
Week 8 chg		98 -27.7 (19.15)	-27.56 (1.73)		97 -35.3 (19.26)	-35.40 (1.71)	-7.85 (-12.6, -3.07) 0.001 [-0.41 (-0.69, -0.12)]
Week 10		96 40.9 (19.85)			97 33.5 (17.54)		
Week 10 chg		96 -30.1 (21.08)	-29.47 (1.73)		97 -36.8 (19.33)	-36.76 (1.71)	-7.29 (-12.1, -2.50) 0.003 [-0.36 (-0.65, -0.08)]
Week 12		94 40.2 (17.60)			95 31.7 (17.30)		
Week 12 chg		94 -31.1 (19.70)	-30.47 (1.74)		95 -38.7 (18.62)	-38.66 (1.72)	-8.19 (-13.0, -3.38) <.001 [-0.43 (-0.72, -0.14)]
Week 14		93 37.4 (19.49)			94 30.0 (17.72)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1048
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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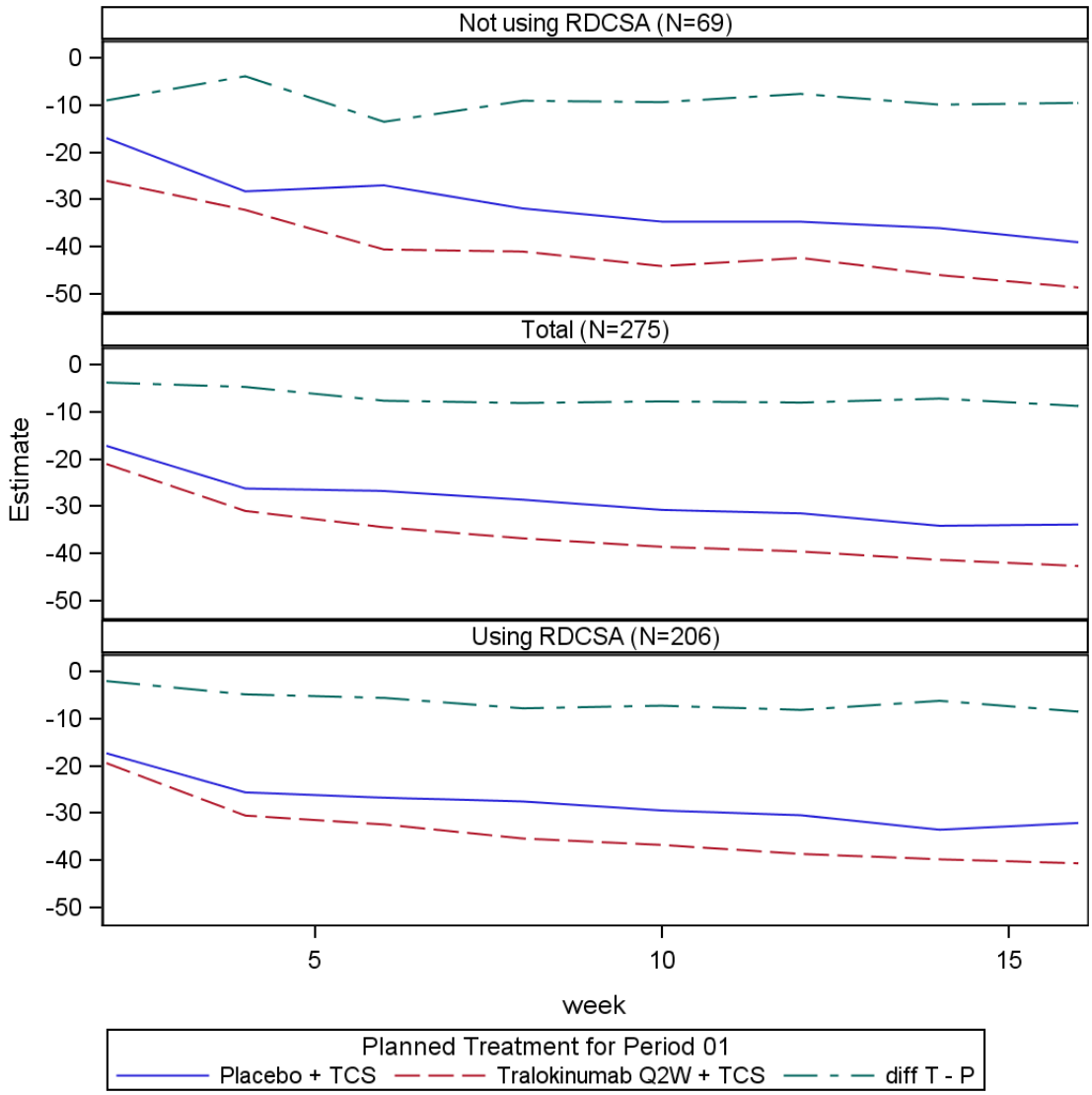
Table 1.17.407.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	93	-33.7 (20.09)	-33.54 (1.74)	94	-40.5 (20.38)	-39.79 (1.72)	-6.26 (-11.1, -1.44) [-0.31 (-0.60, -0.02)]	0.011
Week 16	92	39.1 (18.49)		92	28.8 (16.65)			
Week 16 chg	92	-32.1 (19.18)	-32.10 (1.75)	92	-41.7 (19.24)	-40.64 (1.73)	-8.54 (-13.4, -3.72) [-0.44 (-0.74, -0.15)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1048
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 17:05 LP0162-Payer /p_mmrm3/t_t_csa_g07_46_w16.txt

Figure 1.17.407.4.2: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.17.409.4.1: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score											
Total											
Baseline	137	134	16.4 (6.33)			138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)				132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.15 (0.45)			132	-7.5 (5.92)	-7.56 (0.45)		-0.41 (-1.65, 0.84) 0.520 [-0.07 (-0.31, 0.17)]
Week 4		130	7.8 (6.27)				135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.32 (0.45)			135	-9.0 (6.32)	-9.14 (0.44)		-0.82 (-2.06, 0.42) 0.196 [-0.13 (-0.37, 0.12)]
Week 6		123	7.3 (6.07)				126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.65 (0.45)			126	-10.0 (6.75)	-9.87 (0.45)		-1.22 (-2.48, 0.03) 0.056 [-0.18 (-0.42, 0.07)]
Week 8		127	6.9 (5.70)				128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.97 (0.45)			128	-10.6 (6.29)	-10.39 (0.45)		-1.42 (-2.67, -0.17) 0.026 [-0.22 (-0.46, 0.03)]
Week 12		123	6.8 (5.89)				124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.30 (0.46)			124	-10.6 (5.77)	-10.58 (0.45)		-1.28 (-2.54, -0.02) 0.046 [-0.20 (-0.45, 0.05)]
Week 16		120	6.5 (5.63)				118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.46)			118	-11.0 (5.99)	-11.18 (0.46)		-1.50 (-2.77, -0.23) 0.021 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5842
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.409.4.1: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 15.8 (5.16)		33	33 15.7 (5.32)		
Week 2		35 8.5 (5.22)			32 9.1 (5.87)		
Week 2 chg		35 -6.9 (5.85)	-7.27 (0.74)		32 -6.7 (4.71)	-6.77 (0.78)	0.50 (-1.62, 2.63) 0.641 [0.09 (-0.39, 0.57)]
Week 4		34 6.9 (4.36)			33 7.0 (5.67)		
Week 4 chg		34 -9.1 (6.16)	-8.80 (0.75)		33 -8.7 (5.20)	-8.75 (0.77)	0.04 (-2.08, 2.17) 0.967 [0.01 (-0.47, 0.49)]
Week 6		33 6.9 (5.92)			31 5.7 (4.28)		
Week 6 chg		33 -8.6 (7.71)	-8.62 (0.76)		31 -10.1 (4.74)	-10.06 (0.79)	-1.44 (-3.60, 0.72) 0.189 [-0.22 (-0.72, 0.27)]
Week 8		35 5.9 (3.96)			33 5.7 (4.60)		
Week 8 chg		35 -9.9 (5.66)	-9.71 (0.75)		33 -10.0 (5.19)	-10.03 (0.77)	-0.32 (-2.44, 1.80) 0.766 [-0.06 (-0.53, 0.42)]
Week 12		31 5.6 (4.54)			33 5.8 (4.10)		
Week 12 chg		31 -10.3 (6.07)	-9.69 (0.77)		33 -9.9 (4.82)	-9.97 (0.77)	-0.28 (-2.44, 1.88) 0.799 [-0.05 (-0.54, 0.44)]
Week 16		31 4.7 (3.38)			30 5.5 (3.56)		
Week 16 chg		31 -11.2 (5.22)	-10.92 (0.78)		30 -10.3 (5.13)	-10.46 (0.79)	0.47 (-1.72, 2.66) 0.674 [0.09 (-0.41, 0.59)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5842
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

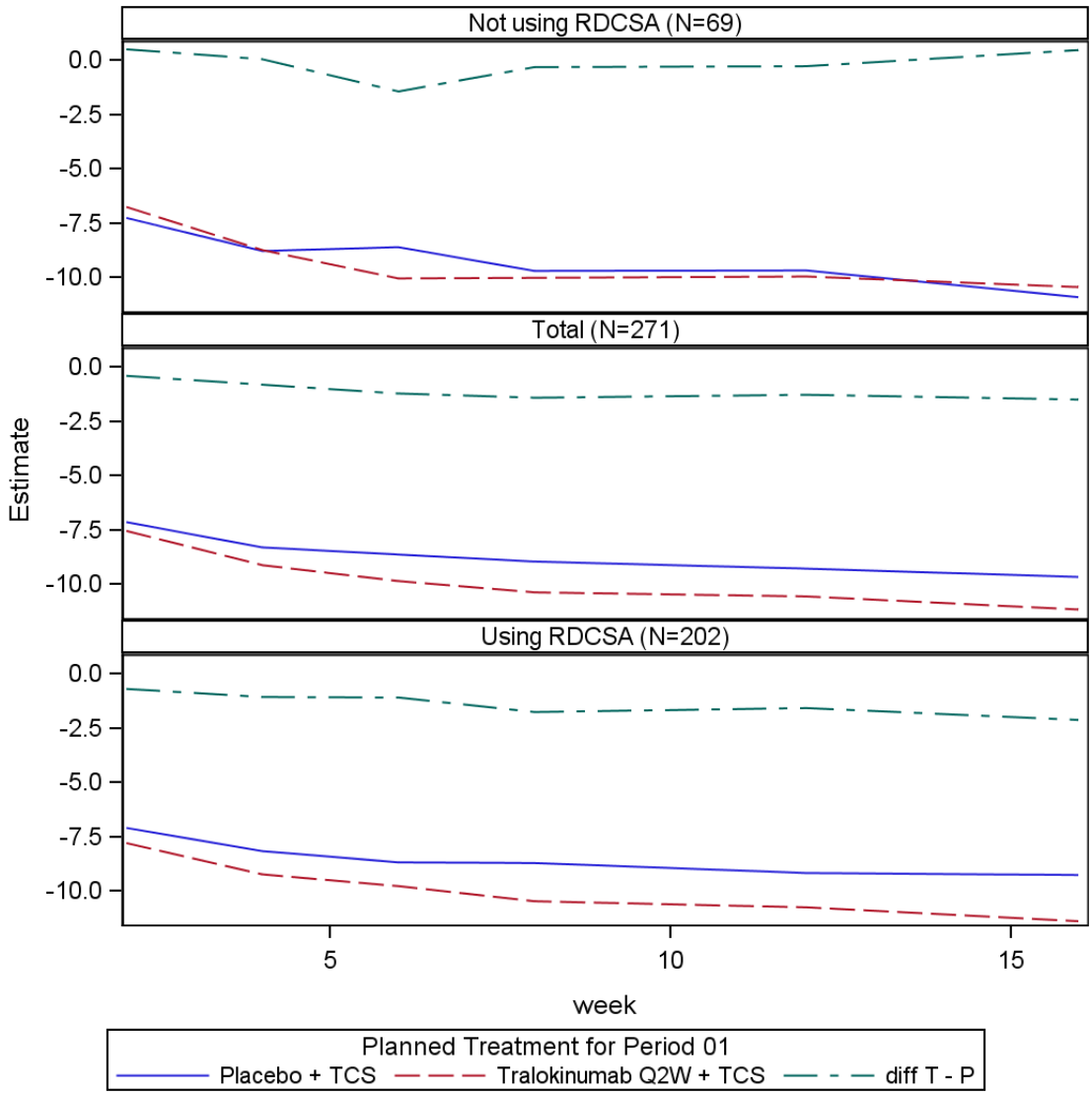
12MAY21 16:34 LP0162-Payer /p_mmrm3/t_t_csa_g09_46_w16.txt

Table 1.17.409.4.1: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA									
Baseline	101	98	16.6 (6.72)		105	104	15.9 (6.89)		
Week 2		96	9.4 (6.88)			100	8.3 (6.28)		
Week 2 chg		96	-7.4 (5.71)	-7.11 (0.54)		100	-7.8 (6.25)	-7.81 (0.53)	-0.70 (-2.20, 0.80) 0.359 [-0.12 (-0.40, 0.16)]
Week 4		96	8.1 (6.82)			102	6.7 (6.11)		
Week 4 chg		96	-8.4 (6.87)	-8.18 (0.55)		102	-9.1 (6.66)	-9.25 (0.53)	-1.07 (-2.57, 0.42) 0.159 [-0.16 (-0.44, 0.12)]
Week 6		90	7.4 (6.16)			95	6.1 (6.22)		
Week 6 chg		90	-9.0 (7.09)	-8.69 (0.55)		95	-9.9 (7.31)	-9.79 (0.54)	-1.10 (-2.61, 0.42) 0.154 [-0.15 (-0.44, 0.14)]
Week 8		92	7.3 (6.22)			95	5.3 (5.30)		
Week 8 chg		92	-9.1 (7.25)	-8.72 (0.55)		95	-10.8 (6.65)	-10.49 (0.54)	-1.76 (-3.27, -0.25) 0.022 [-0.25 (-0.54, 0.03)]
Week 12		92	7.2 (6.26)			91	4.8 (3.85)		
Week 12 chg		92	-9.6 (7.64)	-9.19 (0.55)		91	-10.9 (6.08)	-10.77 (0.54)	-1.58 (-3.10, -0.06) 0.041 [-0.23 (-0.52, 0.06)]
Week 16		89	7.1 (6.12)			88	4.1 (3.94)		
Week 16 chg		89	-9.5 (6.92)	-9.28 (0.55)		88	-11.2 (6.27)	-11.41 (0.54)	-2.13 (-3.66, -0.60) 0.006 [-0.32 (-0.62, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5842
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.409.4.2: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, 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 Prior CSA use, 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 1.17.410.4.1: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total											
Total											
Baseline	137	134	20.9 (5.72)			138	135	21.3 (5.12)			
Week 2		130	15.1 (6.91)				130	13.5 (6.31)			
Week 2 chg		130	-5.9 (6.29)	-5.98	(0.55)		130	-7.7 (5.43)	-7.66	(0.54)	-1.69 (-3.20, -0.17) 0.029 [-0.29 (-0.53, -0.04)]
Week 4		130	13.8 (7.45)				133	11.6 (6.30)			
Week 4 chg		130	-7.1 (7.56)	-7.12	(0.55)		133	-9.7 (6.02)	-9.53	(0.54)	-2.40 (-3.92, -0.89) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123	13.5 (7.81)				124	10.9 (5.95)			
Week 6 chg		123	-7.2 (8.29)	-7.34	(0.55)		124	-10.6 (6.27)	-10.36	(0.55)	-3.02 (-4.56, -1.48) <.001 [-0.41 (-0.66, -0.16)]
Week 8		127	13.1 (7.02)				126	9.9 (5.79)			
Week 8 chg		127	-7.6 (7.95)	-7.73	(0.55)		126	-11.5 (6.10)	-11.20	(0.55)	-3.47 (-5.00, -1.94) <.001 [-0.49 (-0.74, -0.24)]
Week 12		123	13.0 (7.39)				122	9.2 (5.72)			
Week 12 chg		123	-8.0 (8.26)	-7.90	(0.55)		122	-12.4 (6.20)	-11.83	(0.55)	-3.93 (-5.47, -2.39) <.001 [-0.54 (-0.79, -0.28)]
Week 16		120	13.0 (7.69)				116	9.1 (5.58)			
Week 16 chg		120	-8.0 (8.09)	-8.05	(0.56)		116	-12.2 (6.39)	-11.87	(0.56)	-3.82 (-5.37, -2.27) <.001 [-0.52 (-0.78, -0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9320
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 13:42 LP0162-Payer /p_mmrm3/t_t_csa_g10_46_w16.txt

Table 1.17.410.4.1: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 19.9 (5.44)		33	32 21.5 (4.80)			
Week 2		35 14.6 (6.78)			31 13.9 (6.65)			
Week 2 chg		35 -5.2 (7.05)	-5.82 (1.10)		31 -7.6 (4.71)	-7.32 (1.17)	-1.50 (-4.71, 1.70) [-0.25 (-0.73, 0.24)]	0.356
Week 4		34 12.9 (7.69)			32 12.5 (6.00)			
Week 4 chg		34 -7.1 (9.12)	-7.50 (1.11)		32 -9.0 (4.81)	-8.51 (1.16)	-1.01 (-4.21, 2.20) [-0.14 (-0.62, 0.35)]	0.535
Week 6		33 13.5 (8.58)			30 11.4 (5.45)			
Week 6 chg		33 -6.1 (9.36)	-6.85 (1.13)		30 -10.3 (5.05)	-9.81 (1.18)	-2.96 (-6.22, 0.30) [-0.39 (-0.89, 0.11)]	0.074
Week 8		35 11.8 (7.06)			32 10.7 (5.56)			
Week 8 chg		35 -8.0 (8.36)	-8.54 (1.11)		32 -10.8 (5.77)	-10.16 (1.16)	-1.63 (-4.82, 1.57) [-0.22 (-0.71, 0.26)]	0.316
Week 12		31 11.6 (7.60)			32 9.8 (5.46)			
Week 12 chg		31 -8.1 (9.44)	-8.35 (1.14)		32 -11.7 (6.00)	-11.01 (1.16)	-2.66 (-5.91, 0.58) [-0.34 (-0.84, 0.16)]	0.107
Week 16		31 11.3 (7.56)			29 9.8 (5.81)			
Week 16 chg		31 -8.5 (8.08)	-8.54 (1.14)		29 -12.0 (6.32)	-11.43 (1.20)	-2.89 (-6.18, 0.40) [-0.40 (-0.91, 0.11)]	0.084

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9320
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.410.4.1: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA											
Baseline	101	98	21.2 (5.81)			105	103	21.2 (5.24)			
Week 2		95	15.3 (6.99)				99	13.4 (6.23)			
Week 2 chg		95	-6.2 (6.00)	-6.03	(0.63)		99	-7.8 (5.65)	-7.76	(0.62)	-1.73 (-3.46, 0.01) 0.051 [-0.30 (-0.58, -0.01)]
Week 4		96	14.1 (7.39)				101	11.3 (6.40)			
Week 4 chg		96	-7.1 (6.98)	-7.03	(0.63)		101	-9.9 (6.37)	-9.81	(0.61)	-2.78 (-4.52, -1.05) 0.002 [-0.42 (-0.70, -0.14)]
Week 6		90	13.5 (7.55)				94	10.7 (6.12)			
Week 6 chg		90	-7.6 (7.87)	-7.53	(0.64)		94	-10.7 (6.63)	-10.53	(0.62)	-3.00 (-4.75, -1.24) <.001 [-0.41 (-0.70, -0.12)]
Week 8		92	13.6 (6.98)				94	9.6 (5.87)			
Week 8 chg		92	-7.4 (7.83)	-7.45	(0.64)		94	-11.8 (6.22)	-11.51	(0.62)	-4.06 (-5.81, -2.30) <.001 [-0.57 (-0.87, -0.28)]
Week 12		92	13.5 (7.30)				90	9.0 (5.83)			
Week 12 chg		92	-8.0 (7.88)	-7.81	(0.64)		90	-12.6 (6.29)	-12.05	(0.63)	-4.24 (-6.01, -2.48) <.001 [-0.59 (-0.89, -0.30)]
Week 16		89	13.5 (7.69)				87	8.8 (5.51)			
Week 16 chg		89	-7.8 (8.14)	-7.91	(0.64)		87	-12.3 (6.45)	-11.97	(0.64)	-4.07 (-5.84, -2.29) <.001 [-0.55 (-0.85, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9320
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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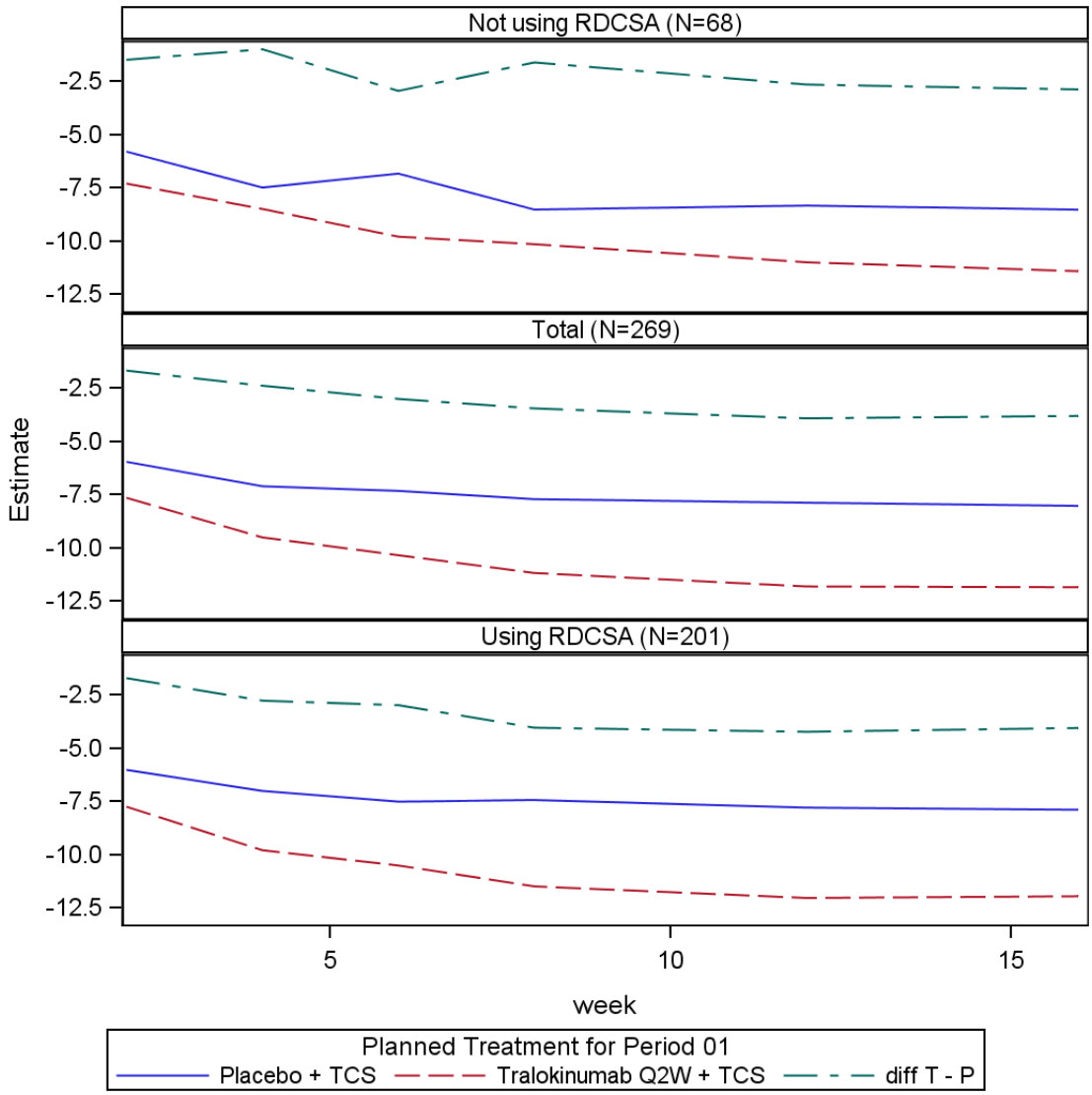
Figure 1.17.410.4.2: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 16



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 Prior CSA use, 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 1.17.414.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 2		137 20.9 (13.94)			138 19.2 (12.75)		
Week 2 chg		137 -12.9 (11.16)	-12.60 (0.81)		138 -12.9 (10.72)	-13.33 (0.81)	-0.73 (-2.98, 1.53) 0.526 [-0.07 (-0.30, 0.17)]
Week 4		134 15.7 (12.58)			137 13.1 (10.37)		
Week 4 chg		134 -18.2 (11.93)	-17.57 (0.81)		137 -18.8 (10.58)	-19.44 (0.81)	-1.86 (-4.13, 0.40) 0.106 [-0.17 (-0.40, 0.07)]
Week 6		132 14.7 (12.40)			134 11.2 (9.67)		
Week 6 chg		132 -19.2 (12.62)	-18.53 (0.82)		134 -20.9 (11.93)	-21.51 (0.81)	-2.98 (-5.25, -0.71) 0.010 [-0.24 (-0.48, -0.00)]
Week 8		133 14.0 (12.73)			130 9.6 (8.49)		
Week 8 chg		133 -19.9 (13.84)	-19.30 (0.82)		130 -22.5 (12.16)	-23.17 (0.82)	-3.88 (-6.15, -1.60) <.001 [-0.30 (-0.54, -0.05)]
Week 10		131 12.5 (11.67)			130 7.6 (7.43)		
Week 10 chg		131 -21.5 (13.93)	-20.61 (0.82)		130 -24.3 (11.55)	-25.02 (0.82)	-4.41 (-6.69, -2.13) <.001 [-0.34 (-0.59, -0.10)]
Week 12		128 12.0 (11.20)			128 7.6 (7.85)		
Week 12 chg		128 -22.2 (14.26)	-21.10 (0.82)		128 -24.7 (12.40)	-25.22 (0.82)	-4.11 (-6.40, -1.83) <.001 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9692
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.414.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 11.2 (11.57)			127 7.0 (8.34)		
Week 14 chg		126 -22.8 (14.69)	-21.89 (0.82)		127 -25.1 (13.29)	-25.74 (0.82)	-3.85 (-6.14, -1.55) 0.001 [-0.27 (-0.52, -0.03)]
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.65 (0.83)		123 -25.9 (12.78)	-26.17 (0.83)	-3.52 (-5.82, -1.22) 0.003 [-0.25 (-0.50, -0.00)]
Week 18		116 10.7 (11.52)			115 5.9 (7.36)		
Week 18 chg		116 -23.6 (14.71)	-22.56 (0.84)		115 -26.4 (12.11)	-26.14 (0.84)	-3.58 (-5.91, -1.25) 0.003 [-0.27 (-0.52, -0.01)]
Week 20		107 10.6 (12.56)			117 5.5 (6.56)		
Week 20 chg		107 -24.1 (15.32)	-22.56 (0.85)		117 -26.9 (11.94)	-26.74 (0.84)	-4.18 (-6.53, -1.84) <.001 [-0.31 (-0.57, -0.04)]
Week 22		112 10.5 (11.17)			114 5.0 (5.93)		
Week 22 chg		112 -24.3 (14.63)	-22.40 (0.84)		114 -27.3 (12.17)	-27.13 (0.84)	-4.73 (-7.08, -2.39) <.001 [-0.35 (-0.61, -0.09)]
Week 24		112 9.9 (11.00)			117 5.3 (7.21)		
Week 24 chg		112 -24.9 (14.38)	-22.80 (0.84)		117 -27.0 (12.11)	-26.99 (0.84)	-4.19 (-6.53, -1.85) <.001 [-0.32 (-0.58, -0.06)]
Week 26		118 9.1 (10.14)			125 5.6 (7.90)		
Week 26 chg		118 -25.5 (13.74)	-23.71 (0.83)		125 -26.5 (12.83)	-27.01 (0.82)	-3.30 (-5.61, -0.99) 0.005 [-0.25 (-0.50, 0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9692
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.414.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 31.9 (13.21)		33	33 30.2 (8.24)		
Week 2		36 19.1 (11.62)			33 15.4 (11.55)		
Week 2 chg		36 -12.8 (10.52)	-12.44 (1.43)		33 -14.8 (10.18)	-15.25 (1.49)	-2.81 (-6.90, 1.29) 0.178 [-0.27 (-0.75, 0.20)]
Week 4		35 12.9 (11.75)			33 11.0 (9.62)		
Week 4 chg		35 -19.3 (12.20)	-18.68 (1.44)		33 -19.2 (10.44)	-19.77 (1.49)	-1.10 (-5.21, 3.02) 0.599 [-0.10 (-0.57, 0.38)]
Week 6		34 12.0 (11.18)			33 8.8 (9.50)		
Week 6 chg		34 -20.6 (13.43)	-19.40 (1.45)		33 -21.3 (11.29)	-22.09 (1.49)	-2.69 (-6.82, 1.44) 0.200 [-0.22 (-0.70, 0.26)]
Week 8		35 10.8 (11.41)			33 7.3 (8.24)		
Week 8 chg		35 -21.5 (13.66)	-20.64 (1.44)		33 -22.8 (10.73)	-23.60 (1.49)	-2.96 (-7.07, 1.16) 0.157 [-0.24 (-0.72, 0.24)]
Week 10		35 9.1 (9.07)			33 4.7 (5.20)		
Week 10 chg		35 -23.1 (12.32)	-22.21 (1.44)		33 -25.5 (9.61)	-26.32 (1.49)	-4.11 (-8.23, 0.00) 0.050 [-0.37 (-0.85, 0.11)]
Week 12		34 8.8 (8.90)			33 5.6 (7.66)		
Week 12 chg		34 -23.6 (11.81)	-22.35 (1.45)		33 -24.6 (10.89)	-25.37 (1.49)	-3.02 (-7.15, 1.11) 0.150 [-0.27 (-0.75, 0.22)]
Week 14		33 8.6 (9.88)			33 4.8 (8.07)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9692
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.414.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	33	-23.4 (13.18)	-22.13 (1.46)	33	-25.4 (11.29)	-26.19 (1.49)	-4.06 (-8.20, 0.07) 0.054 [-0.33 (-0.82, 0.15)]
Week 16	32	7.2 (9.39)		31	4.2 (7.25)		
Week 16 chg	32	-25.0 (12.94)	-23.11 (1.47)	31	-26.2 (11.01)	-26.95 (1.51)	-3.84 (-8.02, 0.34) 0.071 [-0.32 (-0.82, 0.18)]
Week 18	30	7.6 (8.92)		31	2.5 (2.91)		
Week 18 chg	30	-24.3 (12.64)	-22.69 (1.49)	31	-27.8 (9.43)	-27.63 (1.51)	-4.94 (-9.14, -0.73) 0.022 [-0.44 (-0.95, 0.06)]
Week 20	27	7.1 (9.83)		30	3.2 (3.13)		
Week 20 chg	27	-24.6 (12.57)	-22.93 (1.53)	30	-26.8 (8.93)	-26.95 (1.53)	-4.02 (-8.29, 0.25) 0.065 [-0.37 (-0.90, 0.15)]
Week 22	27	6.9 (9.05)		28	2.8 (3.46)		
Week 22 chg	27	-25.3 (12.88)	-23.21 (1.53)	28	-27.2 (9.46)	-27.05 (1.55)	-3.84 (-8.14, 0.47) 0.080 [-0.34 (-0.87, 0.19)]
Week 24	27	7.3 (9.53)		29	2.4 (2.71)		
Week 24 chg	27	-24.9 (13.98)	-22.76 (1.53)	29	-27.7 (8.81)	-27.75 (1.54)	-4.99 (-9.28, -0.70) 0.023 [-0.43 (-0.96, 0.10)]
Week 26	31	5.6 (8.43)		31	4.1 (8.39)		
Week 26 chg	31	-26.6 (12.66)	-24.93 (1.48)	31	-25.8 (11.84)	-27.04 (1.51)	-2.12 (-6.31, 2.08) 0.320 [-0.17 (-0.67, 0.33)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9692
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.414.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA							
Baseline	101	101 34.5 (13.55)		105	105 32.7 (12.35)		
Week 2		101 21.6 (14.67)			105 20.4 (12.92)		
Week 2 chg		101 -12.9 (11.43)	-12.69 (0.98)		105 -12.3 (10.86)	-12.70 (0.96)	-0.01 (-2.71, 2.69) 0.994 [-0.00 (-0.27, 0.27)]
Week 4		99 16.6 (12.78)			104 13.8 (10.56)		
Week 4 chg		99 -17.8 (11.87)	-17.20 (0.98)		104 -18.7 (10.67)	-19.31 (0.96)	-2.11 (-4.82, 0.60) 0.126 [-0.19 (-0.46, 0.09)]
Week 6		98 15.7 (12.72)			101 12.0 (9.65)		
Week 6 chg		98 -18.8 (12.36)	-18.22 (0.98)		101 -20.8 (12.18)	-21.32 (0.97)	-3.10 (-5.82, -0.38) 0.025 [-0.25 (-0.53, 0.03)]
Week 8		98 15.2 (13.03)			97 10.4 (8.48)		
Week 8 chg		98 -19.3 (13.94)	-18.84 (0.98)		97 -22.4 (12.67)	-23.04 (0.98)	-4.19 (-6.92, -1.47) 0.003 [-0.31 (-0.60, -0.03)]
Week 10		96 13.7 (12.29)			97 8.7 (7.82)		
Week 10 chg		96 -20.9 (14.49)	-20.05 (0.99)		97 -23.8 (12.15)	-24.59 (0.98)	-4.54 (-7.28, -1.81) 0.001 [-0.34 (-0.62, -0.06)]
Week 12		94 13.2 (11.76)			95 8.3 (7.82)		
Week 12 chg		94 -21.7 (15.08)	-20.69 (0.99)		95 -24.8 (12.93)	-25.17 (0.98)	-4.48 (-7.22, -1.74) 0.001 [-0.32 (-0.61, -0.03)]
Week 14		93 12.2 (12.02)			94 7.8 (8.34)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9692
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.414.4.1: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	93	-22.6 (15.26)	-21.83 (0.99)	94	-25.0 (13.97)	-25.58 (0.98)	-3.75 (-6.50, -1.00) [-0.26 (-0.54, 0.03)]	0.008
Week 16		92 11.7 (11.87)			92 7.1 (7.65)			
Week 16 chg	92	-23.3 (15.61)	-22.52 (0.99)	92	-25.7 (13.37)	-25.91 (0.98)	-3.39 (-6.15, -0.64) [-0.23 (-0.52, 0.06)]	0.016
Week 18		86 11.8 (12.15)			84 7.1 (8.08)			
Week 18 chg	86	-23.3 (15.43)	-22.53 (1.01)	84	-25.8 (12.97)	-25.60 (1.00)	-3.08 (-5.88, -0.28) [-0.22 (-0.52, 0.09)]	0.031
Week 20		80 11.7 (13.21)			87 6.3 (7.22)			
Week 20 chg	80	-23.9 (16.21)	-22.43 (1.02)	87	-27.0 (12.87)	-26.66 (0.99)	-4.22 (-7.03, -1.42) [-0.29 (-0.60, 0.02)]	0.003
Week 22		85 11.7 (11.56)			86 5.7 (6.38)			
Week 22 chg	85	-24.0 (15.20)	-22.14 (1.01)	86	-27.4 (12.98)	-27.15 (1.00)	-5.01 (-7.80, -2.21) [-0.35 (-0.66, -0.05)]	<.001
Week 24		85 10.7 (11.36)			88 6.3 (7.95)			
Week 24 chg	85	-24.8 (14.59)	-22.82 (1.01)	88	-26.8 (13.05)	-26.74 (0.99)	-3.93 (-6.72, -1.14) [-0.28 (-0.58, 0.02)]	0.006
Week 26		87 10.3 (10.46)			94 6.2 (7.71)			
Week 26 chg	87	-25.2 (14.16)	-23.29 (1.00)	94	-26.7 (13.19)	-27.00 (0.98)	-3.70 (-6.47, -0.94) [-0.27 (-0.56, 0.02)]	0.009

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9692
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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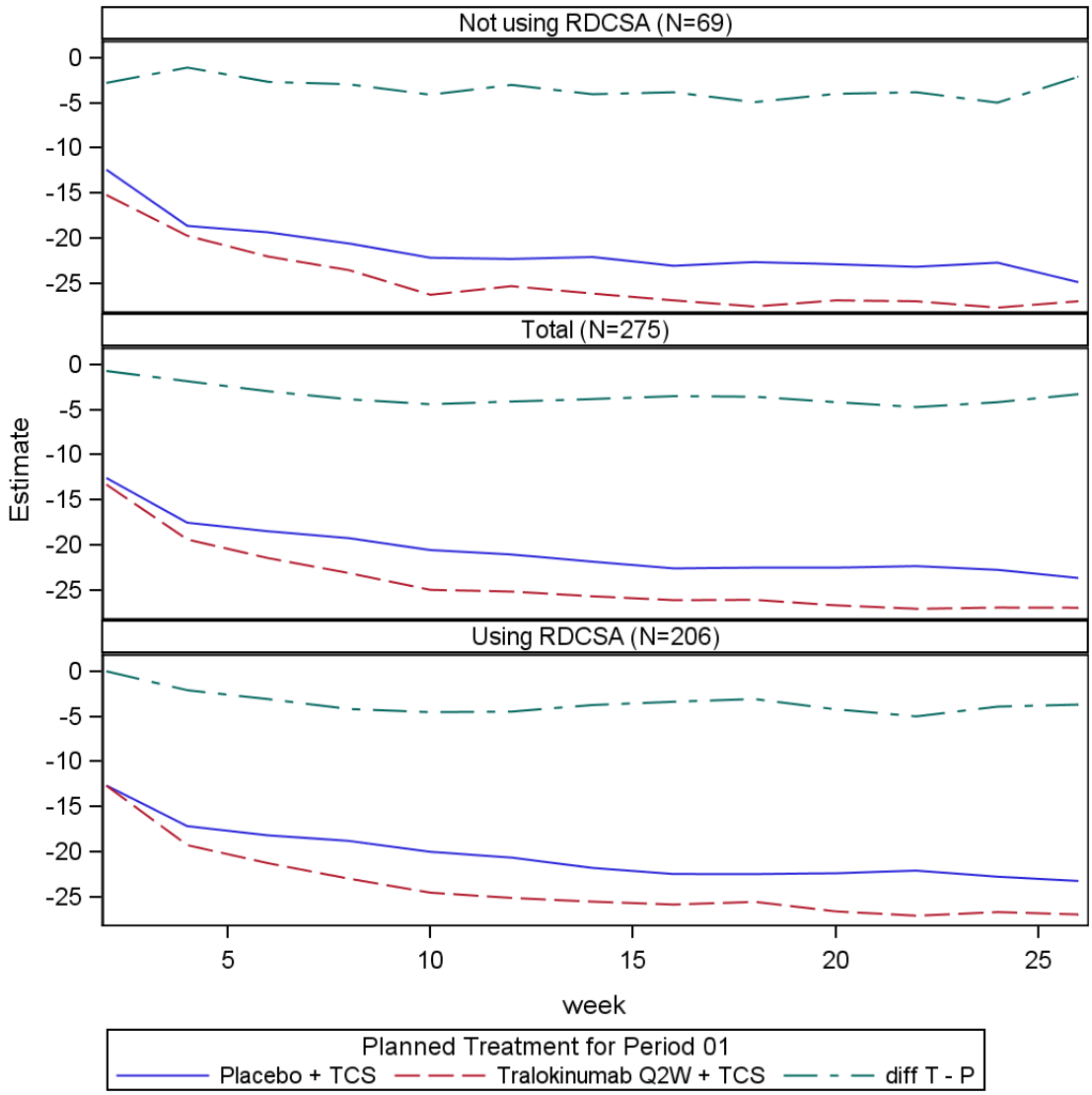
Figure 1.17.414.4.2: Total, RDSCA Use, change in EASI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)									
Total									
Baseline	137	136	7.5 (1.37)		138	137	7.3 (1.45)		
Week 1		135	6.3 (1.69)			136	6.0 (1.78)		
Week 1 chg		135	-1.1 (1.34)	-1.12 (0.18)		136	-1.2 (1.31)	-1.22 (0.18)	-0.10 (-0.60, 0.40) 0.699 [-0.07 (-0.31, 0.16)]
Week 2		134	5.8 (1.97)			132	5.4 (2.11)		
Week 2 chg		134	-1.7 (1.78)	-1.67 (0.18)		132	-1.9 (1.67)	-1.92 (0.18)	-0.24 (-0.74, 0.26) 0.338 [-0.14 (-0.38, 0.10)]
Week 3		133	5.3 (2.17)			131	4.8 (2.08)		
Week 3 chg		133	-2.2 (2.12)	-2.11 (0.18)		131	-2.5 (1.84)	-2.53 (0.18)	-0.42 (-0.92, 0.08) 0.097 [-0.21 (-0.46, 0.03)]
Week 4		130	5.1 (2.25)			133	4.4 (2.14)		
Week 4 chg		130	-2.4 (2.14)	-2.29 (0.18)		133	-2.8 (1.92)	-2.87 (0.18)	-0.58 (-1.08, -0.08) 0.023 [-0.29 (-0.53, -0.04)]
Week 5		131	4.9 (2.37)			129	4.2 (2.15)		
Week 5 chg		131	-2.6 (2.26)	-2.53 (0.18)		129	-3.1 (1.92)	-3.16 (0.18)	-0.63 (-1.13, -0.13) 0.014 [-0.30 (-0.54, -0.06)]
Week 6		130	4.8 (2.35)			129	4.2 (2.16)		
Week 6 chg		130	-2.7 (2.25)	-2.55 (0.18)		129	-3.1 (1.99)	-3.15 (0.18)	-0.61 (-1.11, -0.10) 0.018 [-0.29 (-0.53, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7	129	4.7 (2.24)		128	4.0 (2.13)			
Week 7 chg	129	-2.8 (2.25)	-2.69 (0.18)	128	-3.3 (2.05)	-3.38 (0.18)	-0.69 (-1.19, -0.19) [-0.32 (-0.57, -0.07)]	0.007
Week 8	127	4.7 (2.32)		125	3.7 (2.10)			
Week 8 chg	127	-2.8 (2.27)	-2.69 (0.18)	125	-3.7 (1.96)	-3.65 (0.18)	-0.96 (-1.46, -0.46) [-0.45 (-0.70, -0.20)]	<.001
Week 9	127	4.6 (2.37)		127	3.6 (2.10)			
Week 9 chg	127	-2.9 (2.32)	-2.76 (0.18)	127	-3.7 (2.03)	-3.71 (0.18)	-0.95 (-1.45, -0.45) [-0.44 (-0.69, -0.19)]	<.001
Week 10	125	4.5 (2.42)		122	3.6 (2.11)			
Week 10 chg	125	-2.9 (2.39)	-2.84 (0.18)	122	-3.7 (1.93)	-3.70 (0.18)	-0.87 (-1.37, -0.36) [-0.40 (-0.65, -0.15)]	<.001
Week 11	128	4.4 (2.41)		126	3.5 (2.15)			
Week 11 chg	128	-3.1 (2.40)	-3.03 (0.18)	126	-3.7 (1.97)	-3.76 (0.18)	-0.73 (-1.23, -0.23) [-0.33 (-0.58, -0.09)]	0.004
Week 12	123	4.4 (2.36)		121	3.5 (2.08)			
Week 12 chg	123	-3.1 (2.41)	-2.99 (0.18)	121	-3.8 (2.06)	-3.82 (0.18)	-0.83 (-1.33, -0.32) [-0.37 (-0.62, -0.12)]	0.001
Week 13	116	4.3 (2.38)		120	3.3 (2.06)			
Week 13 chg	116	-3.3 (2.35)	-3.05 (0.18)	120	-4.0 (2.09)	-3.92 (0.18)	-0.87 (-1.38, -0.37) [-0.39 (-0.65, -0.14)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	123	4.2 (2.38)		123	3.4 (2.13)			
Week 14 chg	123	-3.3 (2.33)	-3.11 (0.18)	123	-3.9 (2.12)	-3.85 (0.18)	-0.74 (-1.25, -0.24) [-0.33 (-0.59, -0.08)]	0.004
Week 15	123	4.2 (2.31)		123	3.4 (2.11)			
Week 15 chg	123	-3.3 (2.32)	-3.17 (0.18)	123	-4.0 (2.15)	-3.93 (0.18)	-0.76 (-1.26, -0.25) [-0.34 (-0.59, -0.09)]	0.003
Week 16	121	4.2 (2.29)		122	3.4 (2.05)			
Week 16 chg	121	-3.3 (2.35)	-3.09 (0.18)	122	-3.9 (2.06)	-3.95 (0.18)	-0.85 (-1.36, -0.35) [-0.39 (-0.64, -0.13)]	<.001
Week 17	121	4.3 (2.46)		121	3.4 (2.13)			
Week 17 chg	121	-3.2 (2.49)	-3.09 (0.18)	121	-3.9 (2.04)	-3.93 (0.18)	-0.84 (-1.35, -0.34) [-0.37 (-0.63, -0.12)]	0.001
Week 18	120	4.4 (2.51)		123	3.3 (2.12)			
Week 18 chg	120	-3.2 (2.46)	-3.04 (0.18)	123	-4.0 (2.11)	-3.96 (0.18)	-0.93 (-1.43, -0.42) [-0.40 (-0.66, -0.15)]	<.001
Week 19	119	4.3 (2.65)		117	3.1 (2.11)			
Week 19 chg	119	-3.3 (2.55)	-3.09 (0.18)	117	-4.2 (2.19)	-4.16 (0.18)	-1.07 (-1.58, -0.57) [-0.45 (-0.71, -0.19)]	<.001
Week 20	120	4.3 (2.68)		118	3.0 (2.02)			
Week 20 chg	120	-3.3 (2.61)	-3.08 (0.18)	118	-4.2 (2.13)	-4.13 (0.18)	-1.05 (-1.56, -0.54) [-0.44 (-0.70, -0.18)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21	118	4.2 (2.59)		115	3.0 (1.94)		
Week 21 chg	118	-3.4 (2.59)	-3.21 (0.18)	115	-4.3 (2.07)	-4.22 (0.18)	-1.01 (-1.52, -0.50) <.001 [-0.43 (-0.69, -0.17)]
Week 22	120	4.2 (2.64)		116	3.0 (1.90)		
Week 22 chg	120	-3.4 (2.64)	-3.23 (0.18)	116	-4.2 (2.06)	-4.23 (0.18)	-1.01 (-1.51, -0.50) <.001 [-0.42 (-0.68, -0.17)]
Week 23	120	4.1 (2.62)		114	3.0 (1.94)		
Week 23 chg	120	-3.5 (2.58)	-3.28 (0.18)	114	-4.3 (2.15)	-4.23 (0.18)	-0.95 (-1.46, -0.44) <.001 [-0.40 (-0.66, -0.14)]
Week 24	120	4.1 (2.52)		112	2.9 (1.92)		
Week 24 chg	120	-3.4 (2.53)	-3.26 (0.18)	112	-4.3 (2.13)	-4.28 (0.18)	-1.02 (-1.53, -0.51) <.001 [-0.43 (-0.69, -0.17)]
Week 25	114	3.8 (2.46)		115	2.9 (1.90)		
Week 25 chg	114	-3.8 (2.50)	-3.46 (0.18)	115	-4.3 (2.08)	-4.34 (0.18)	-0.88 (-1.39, -0.37) <.001 [-0.38 (-0.65, -0.12)]
Week 26	112	3.9 (2.49)		118	3.0 (1.91)		
Week 26 chg	112	-3.6 (2.56)	-3.32 (0.18)	118	-4.3 (2.11)	-4.28 (0.18)	-0.96 (-1.47, -0.45) <.001 [-0.41 (-0.67, -0.15)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 7.4 (1.48)		33	33 7.0 (1.33)		
Week 1		35 5.8 (1.77)			33 6.0 (1.76)		
Week 1 chg		35 -1.5 (1.54)	-1.43 (0.33)		33 -1.1 (1.21)	-1.09 (0.35)	0.34 (-0.62, 1.30) 0.481 [0.25 (-0.23, 0.72)]
Week 2		36 5.4 (1.91)			32 5.3 (1.92)		
Week 2 chg		36 -2.0 (1.70)	-1.92 (0.33)		32 -1.7 (1.46)	-1.76 (0.35)	0.16 (-0.80, 1.12) 0.743 [0.10 (-0.38, 0.58)]
Week 3		35 4.7 (1.89)			31 4.9 (2.03)		
Week 3 chg		35 -2.7 (2.00)	-2.52 (0.33)		31 -2.1 (1.66)	-2.18 (0.35)	0.35 (-0.61, 1.31) 0.475 [0.19 (-0.30, 0.67)]
Week 4		34 4.7 (2.08)			32 4.5 (2.10)		
Week 4 chg		34 -2.6 (2.21)	-2.41 (0.34)		32 -2.5 (1.70)	-2.59 (0.35)	-0.18 (-1.14, 0.78) 0.708 [-0.09 (-0.58, 0.39)]
Week 5		35 4.6 (2.26)			33 4.2 (2.02)		
Week 5 chg		35 -2.8 (2.33)	-2.68 (0.33)		33 -2.9 (1.74)	-2.93 (0.35)	-0.25 (-1.21, 0.71) 0.604 [-0.12 (-0.60, 0.35)]
Week 6		34 4.5 (2.39)			32 4.2 (2.19)		
Week 6 chg		34 -2.8 (2.38)	-2.63 (0.34)		32 -2.8 (1.96)	-2.90 (0.35)	-0.27 (-1.23, 0.69) 0.579 [-0.12 (-0.61, 0.36)]
Week 7		34 4.2 (2.19)			32 4.2 (2.17)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	34	-3.2 (2.39)	-2.95 (0.34)	32	-2.8 (2.03)	-2.92 (0.35)	0.02 (-0.94, 0.99) 0.960 [0.01 (-0.47, 0.49)]
Week 8	32	4.1 (2.28)		31	3.7 (2.25)		
Week 8 chg	32	-3.2 (2.35)	-3.00 (0.34)	31	-3.3 (1.92)	-3.33 (0.35)	-0.33 (-1.29, 0.64) 0.507 [-0.15 (-0.65, 0.34)]
Week 9	34	4.0 (2.18)		33	3.7 (2.22)		
Week 9 chg	34	-3.3 (2.30)	-3.12 (0.34)	33	-3.3 (2.02)	-3.40 (0.35)	-0.28 (-1.24, 0.68) 0.560 [-0.13 (-0.61, 0.35)]
Week 10	33	4.0 (2.15)		30	3.8 (2.20)		
Week 10 chg	33	-3.3 (2.29)	-3.24 (0.34)	30	-3.2 (1.94)	-3.31 (0.35)	-0.08 (-1.04, 0.89) 0.878 [-0.04 (-0.53, 0.46)]
Week 11	34	3.7 (2.02)		32	3.5 (2.31)		
Week 11 chg	34	-3.7 (2.15)	-3.49 (0.34)	32	-3.4 (2.01)	-3.56 (0.35)	-0.08 (-1.04, 0.89) 0.874 [-0.04 (-0.52, 0.45)]
Week 12	33	3.8 (2.16)		32	3.6 (2.14)		
Week 12 chg	33	-3.6 (2.21)	-3.37 (0.34)	32	-3.4 (1.90)	-3.53 (0.35)	-0.16 (-1.13, 0.80) 0.735 [-0.08 (-0.57, 0.41)]
Week 13	32	3.8 (1.98)		31	3.6 (2.18)		
Week 13 chg	32	-3.5 (2.08)	-3.42 (0.34)	31	-3.4 (2.01)	-3.50 (0.35)	-0.08 (-1.05, 0.89) 0.871 [-0.04 (-0.53, 0.46)]
Week 14	33	3.8 (1.98)		30	3.4 (2.26)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	33	-3.6 (1.93)	-3.49 (0.34)	30	-3.7 (1.89)	-3.62 (0.35)	-0.13 (-1.10, 0.84) [-0.07 (-0.56, 0.43)]	0.791
Week 15	33	3.8 (1.85)		31	3.2 (2.11)			
Week 15 chg	33	-3.6 (2.05)	-3.49 (0.34)	31	-3.8 (2.02)	-3.89 (0.35)	-0.41 (-1.37, 0.56) [-0.20 (-0.69, 0.29)]	0.406
Week 16	32	3.8 (1.95)		31	3.4 (1.97)			
Week 16 chg	32	-3.5 (2.15)	-3.45 (0.34)	31	-3.6 (2.03)	-3.84 (0.35)	-0.40 (-1.37, 0.57) [-0.19 (-0.69, 0.30)]	0.419
Week 17	32	3.9 (2.10)		30	3.3 (1.97)			
Week 17 chg	32	-3.5 (2.24)	-3.47 (0.34)	30	-3.7 (1.82)	-3.87 (0.35)	-0.40 (-1.37, 0.57) [-0.19 (-0.69, 0.31)]	0.420
Week 18	32	4.0 (2.12)		30	3.3 (2.12)			
Week 18 chg	32	-3.4 (2.25)	-3.38 (0.34)	30	-3.7 (2.00)	-3.81 (0.35)	-0.43 (-1.41, 0.54) [-0.20 (-0.70, 0.30)]	0.377
Week 19	32	3.7 (2.26)		30	3.2 (2.01)			
Week 19 chg	32	-3.6 (2.22)	-3.63 (0.34)	30	-3.8 (1.87)	-3.93 (0.35)	-0.30 (-1.27, 0.67) [-0.15 (-0.64, 0.35)]	0.542
Week 20	32	3.8 (2.38)		30	3.2 (1.96)			
Week 20 chg	32	-3.5 (2.44)	-3.52 (0.34)	30	-3.8 (1.91)	-3.91 (0.35)	-0.39 (-1.36, 0.58) [-0.18 (-0.68, 0.32)]	0.426
Week 21	31	3.7 (2.21)		30	3.0 (2.05)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 12:37 LP0162-Payer /p_mmrm3/t_t_csa_g16_46_w26.txt

Table 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 21 chg	31	-3.7 (2.31)	-3.65 (0.34)	30	-4.0 (1.90)	-4.10 (0.35)	-0.45 (-1.42, 0.53) [-0.21 (-0.71, 0.29)]	0.366
Week 22	32	3.8 (2.58)		31	3.0 (2.10)			
Week 22 chg	32	-3.6 (2.61)	-3.62 (0.34)	31	-4.0 (2.01)	-4.08 (0.35)	-0.46 (-1.43, 0.50) [-0.20 (-0.69, 0.30)]	0.345
Week 23	32	3.6 (2.32)		30	3.0 (2.02)			
Week 23 chg	32	-3.8 (2.16)	-3.82 (0.34)	30	-4.0 (1.87)	-4.10 (0.35)	-0.28 (-1.25, 0.69) [-0.14 (-0.64, 0.36)]	0.571
Week 24	32	3.6 (2.24)		30	3.1 (1.97)			
Week 24 chg	32	-3.8 (2.24)	-3.76 (0.34)	30	-3.9 (1.79)	-4.03 (0.35)	-0.26 (-1.23, 0.71) [-0.13 (-0.63, 0.37)]	0.593
Week 25	30	3.1 (1.77)		30	3.1 (2.03)			
Week 25 chg	30	-4.2 (1.96)	-4.13 (0.34)	30	-4.0 (1.87)	-4.04 (0.35)	0.09 (-0.89, 1.06) [0.05 (-0.46, 0.55)]	0.858
Week 26	30	3.4 (1.99)		31	3.1 (1.91)			
Week 26 chg	30	-4.0 (2.05)	-3.91 (0.34)	31	-3.9 (1.75)	-4.00 (0.35)	-0.09 (-1.06, 0.89) [-0.04 (-0.55, 0.46)]	0.862

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

12MAY21 12:37 LP0162-Payer /p_mmrm3/t_t_csa_g16_46_w26.txt

Table 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA											
Baseline	101	100	7.5 (1.34)			105	104	7.3 (1.49)			
Week 1		100	6.5 (1.64)				103	6.1 (1.80)			
Week 1 chg		100	-1.0 (1.25)	-1.02	(0.21)		103	-1.3 (1.34)	-1.26	(0.21)	-0.24 (-0.83, 0.34) 0.412 [-0.19 (-0.46, 0.09)]
Week 2		98	5.9 (1.99)				100	5.4 (2.17)			
Week 2 chg		98	-1.6 (1.80)	-1.59	(0.21)		100	-2.0 (1.73)	-1.96	(0.21)	-0.38 (-0.96, 0.21) 0.208 [-0.21 (-0.49, 0.07)]
Week 3		98	5.5 (2.22)				100	4.7 (2.10)			
Week 3 chg		98	-2.0 (2.14)	-1.96	(0.21)		100	-2.6 (1.88)	-2.65	(0.21)	-0.68 (-1.27, -0.10) 0.023 [-0.34 (-0.62, -0.06)]
Week 4		96	5.3 (2.30)				101	4.4 (2.16)			
Week 4 chg		96	-2.3 (2.12)	-2.25	(0.21)		101	-2.9 (1.98)	-2.96	(0.21)	-0.71 (-1.30, -0.12) 0.018 [-0.35 (-0.63, -0.06)]
Week 5		96	5.0 (2.41)				96	4.2 (2.20)			
Week 5 chg		96	-2.6 (2.25)	-2.47	(0.21)		96	-3.2 (1.98)	-3.23	(0.21)	-0.76 (-1.34, -0.17) 0.012 [-0.36 (-0.64, -0.07)]
Week 6		96	4.9 (2.33)				97	4.2 (2.16)			
Week 6 chg		96	-2.6 (2.21)	-2.52	(0.21)		97	-3.2 (1.99)	-3.23	(0.21)	-0.71 (-1.30, -0.12) 0.018 [-0.34 (-0.62, -0.05)]
Week 7		95	4.8 (2.25)				96	3.9 (2.12)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	95	-2.7 (2.20)	-2.60 (0.21)	96	-3.5 (2.03)	-3.53 (0.21)	-0.93 (-1.52, -0.34) [-0.44 (-0.73, -0.15)]	0.002
Week 8	95	4.9 (2.31)		94	3.6 (2.06)			
Week 8 chg	95	-2.7 (2.23)	-2.58 (0.21)	94	-3.8 (1.96)	-3.75 (0.21)	-1.17 (-1.76, -0.58) [-0.56 (-0.85, -0.27)]	<.001
Week 9	93	4.9 (2.41)		94	3.6 (2.08)			
Week 9 chg	93	-2.7 (2.32)	-2.63 (0.21)	94	-3.8 (2.02)	-3.81 (0.21)	-1.18 (-1.77, -0.59) [-0.54 (-0.83, -0.25)]	<.001
Week 10	92	4.7 (2.49)		92	3.6 (2.09)			
Week 10 chg	92	-2.8 (2.42)	-2.70 (0.21)	92	-3.8 (1.92)	-3.83 (0.21)	-1.13 (-1.72, -0.54) [-0.52 (-0.81, -0.23)]	<.001
Week 11	94	4.6 (2.50)		94	3.6 (2.11)			
Week 11 chg	94	-2.9 (2.46)	-2.86 (0.21)	94	-3.8 (1.96)	-3.82 (0.21)	-0.95 (-1.54, -0.36) [-0.43 (-0.72, -0.14)]	0.002
Week 12	90	4.6 (2.41)		89	3.5 (2.07)			
Week 12 chg	90	-3.0 (2.47)	-2.86 (0.21)	89	-3.9 (2.11)	-3.90 (0.21)	-1.04 (-1.63, -0.45) [-0.45 (-0.75, -0.16)]	<.001
Week 13	84	4.5 (2.49)		89	3.2 (2.02)			
Week 13 chg	84	-3.1 (2.45)	-2.91 (0.22)	89	-4.2 (2.09)	-4.05 (0.21)	-1.14 (-1.73, -0.54) [-0.50 (-0.80, -0.20)]	<.001
Week 14	90	4.4 (2.51)		93	3.4 (2.10)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	90	-3.1 (2.47)	-2.98 (0.21)	93	-4.0 (2.19)	-3.92 (0.21)	-0.94 (-1.53, -0.35) [-0.40 (-0.70, -0.11)]	0.002
Week 15	90	4.4 (2.45)		92	3.4 (2.11)			
Week 15 chg	90	-3.2 (2.42)	-3.06 (0.21)	92	-4.0 (2.20)	-3.94 (0.21)	-0.88 (-1.47, -0.28) [-0.38 (-0.67, -0.09)]	0.004
Week 16	89	4.4 (2.39)		91	3.4 (2.09)			
Week 16 chg	89	-3.2 (2.42)	-2.97 (0.21)	91	-4.0 (2.08)	-3.98 (0.21)	-1.01 (-1.60, -0.42) [-0.45 (-0.74, -0.15)]	<.001
Week 17	89	4.5 (2.57)		91	3.4 (2.18)			
Week 17 chg	89	-3.2 (2.57)	-2.95 (0.21)	91	-4.0 (2.12)	-3.95 (0.21)	-1.00 (-1.59, -0.40) [-0.42 (-0.72, -0.13)]	0.001
Week 18	88	4.6 (2.64)		93	3.3 (2.13)			
Week 18 chg	88	-3.1 (2.54)	-2.92 (0.21)	93	-4.1 (2.14)	-4.01 (0.21)	-1.09 (-1.69, -0.50) [-0.47 (-0.76, -0.17)]	<.001
Week 19	87	4.5 (2.76)		87	3.0 (2.16)			
Week 19 chg	87	-3.1 (2.65)	-2.89 (0.22)	87	-4.3 (2.29)	-4.23 (0.21)	-1.34 (-1.93, -0.74) [-0.54 (-0.84, -0.24)]	<.001
Week 20	88	4.5 (2.78)		88	3.0 (2.05)			
Week 20 chg	88	-3.1 (2.68)	-2.92 (0.21)	88	-4.3 (2.19)	-4.19 (0.21)	-1.27 (-1.87, -0.68) [-0.52 (-0.82, -0.22)]	<.001
Week 21	87	4.3 (2.71)		85	3.0 (1.91)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.416.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	87	-3.3 (2.69)	-3.05 (0.22)	85	-4.4 (2.13)	-4.26 (0.21)	-1.20 (-1.80, -0.60) <.001 [-0.50 (-0.80, -0.19)]
Week 22	88	4.3 (2.66)		85	3.0 (1.84)		
Week 22 chg	88	-3.3 (2.66)	-3.09 (0.21)	85	-4.3 (2.09)	-4.28 (0.21)	-1.19 (-1.79, -0.59) <.001 [-0.50 (-0.80, -0.19)]
Week 23	88	4.3 (2.71)		84	2.9 (1.92)		
Week 23 chg	88	-3.3 (2.71)	-3.09 (0.21)	84	-4.4 (2.24)	-4.27 (0.21)	-1.18 (-1.78, -0.58) <.001 [-0.47 (-0.78, -0.17)]
Week 24	88	4.3 (2.60)		82	2.9 (1.92)		
Week 24 chg	88	-3.3 (2.64)	-3.08 (0.21)	82	-4.4 (2.23)	-4.36 (0.21)	-1.28 (-1.87, -0.68) <.001 [-0.52 (-0.83, -0.22)]
Week 25	84	4.0 (2.63)		85	2.8 (1.86)		
Week 25 chg	84	-3.6 (2.65)	-3.21 (0.22)	85	-4.4 (2.15)	-4.44 (0.21)	-1.23 (-1.82, -0.63) <.001 [-0.51 (-0.81, -0.20)]
Week 26	82	4.1 (2.63)		87	2.9 (1.92)		
Week 26 chg	82	-3.4 (2.72)	-3.11 (0.22)	87	-4.4 (2.23)	-4.37 (0.21)	-1.26 (-1.86, -0.67) <.001 [-0.51 (-0.82, -0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.8627
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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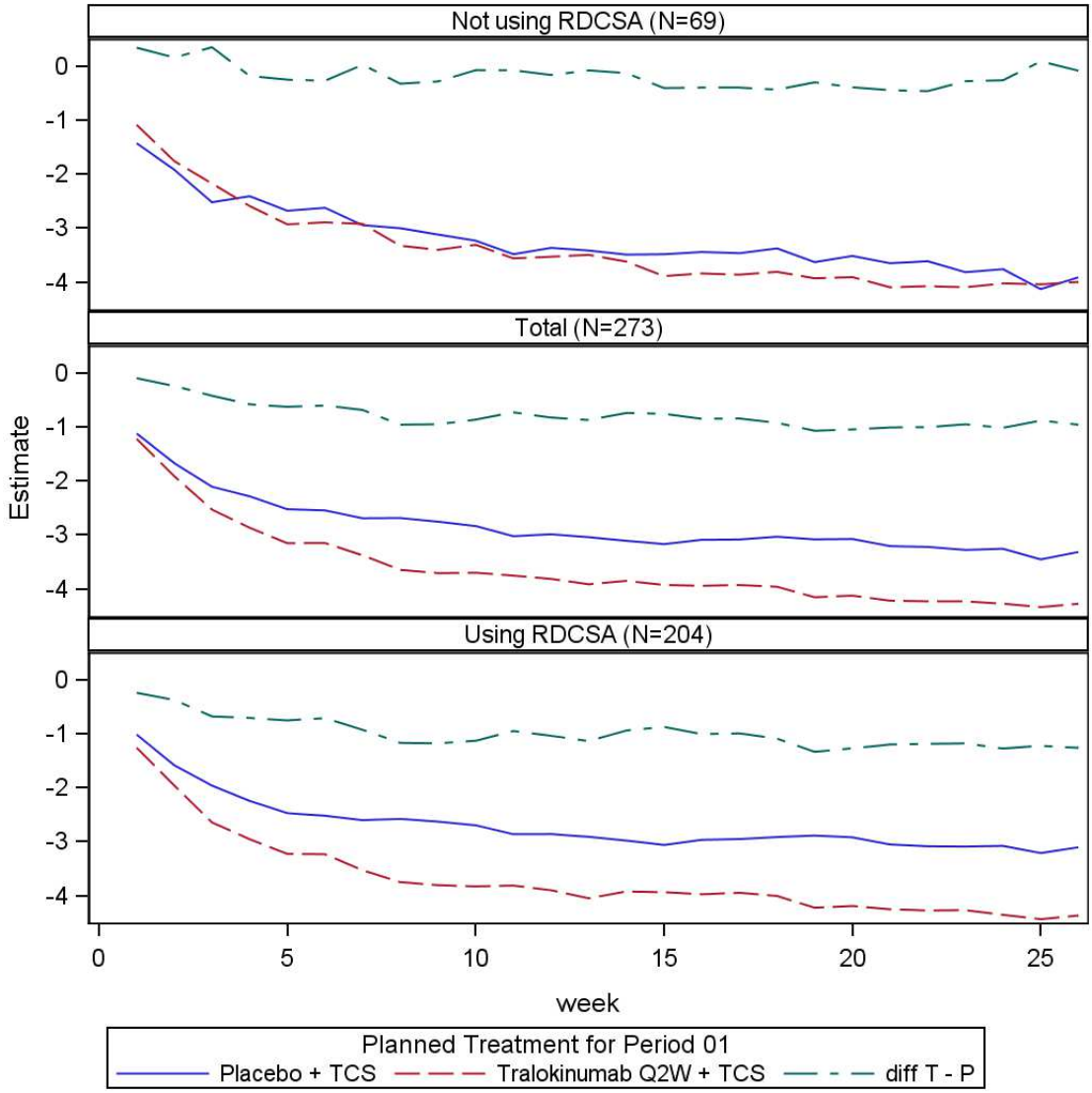
Figure 1.17.416.4.2: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 1		135 5.8 (2.01)			136 5.2 (2.21)		
Week 1 chg		135 -1.1 (1.50)	-1.05 (0.18)		136 -1.1 (1.45)	-1.15 (0.18)	-0.10 (-0.61, 0.42) 0.715 [-0.07 (-0.30, 0.17)]
Week 2		134 5.2 (2.29)			132 4.5 (2.45)		
Week 2 chg		134 -1.7 (1.98)	-1.67 (0.18)		132 -1.8 (1.80)	-1.85 (0.19)	-0.18 (-0.70, 0.34) 0.502 [-0.09 (-0.33, 0.15)]
Week 3		133 4.7 (2.36)			131 3.9 (2.35)		
Week 3 chg		133 -2.2 (2.17)	-2.12 (0.19)		131 -2.4 (2.01)	-2.49 (0.19)	-0.37 (-0.89, 0.15) 0.165 [-0.18 (-0.42, 0.07)]
Week 4		130 4.5 (2.48)			133 3.6 (2.39)		
Week 4 chg		130 -2.4 (2.23)	-2.25 (0.19)		133 -2.7 (2.06)	-2.79 (0.19)	-0.54 (-1.06, -0.02) 0.041 [-0.25 (-0.50, -0.01)]
Week 5		131 4.2 (2.55)			129 3.3 (2.42)		
Week 5 chg		131 -2.7 (2.37)	-2.54 (0.19)		129 -3.0 (2.16)	-3.13 (0.19)	-0.59 (-1.11, -0.07) 0.027 [-0.26 (-0.50, -0.01)]
Week 6		130 4.2 (2.52)			129 3.3 (2.42)		
Week 6 chg		130 -2.7 (2.36)	-2.50 (0.19)		129 -3.1 (2.24)	-3.21 (0.19)	-0.71 (-1.23, -0.19) 0.008 [-0.31 (-0.55, -0.06)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7	129	129 3.9 (2.43)		128	128 3.1 (2.37)		
Week 7 chg	129	129 -3.0 (2.38)	-2.77 (0.19)	128	128 -3.3 (2.28)	-3.41 (0.19)	-0.64 (-1.16, -0.12) 0.016 [-0.27 (-0.52, -0.03)]
Week 8	127	127 3.9 (2.46)		125	125 2.8 (2.29)		
Week 8 chg	127	127 -3.0 (2.32)	-2.75 (0.19)	125	125 -3.6 (2.26)	-3.65 (0.19)	-0.90 (-1.42, -0.38) <.001 [-0.39 (-0.64, -0.14)]
Week 9	127	127 3.8 (2.49)		127	127 2.6 (2.22)		
Week 9 chg	127	127 -3.1 (2.33)	-2.89 (0.19)	127	127 -3.7 (2.23)	-3.84 (0.19)	-0.95 (-1.47, -0.43) <.001 [-0.41 (-0.66, -0.17)]
Week 10	125	125 3.7 (2.54)		122	122 2.7 (2.29)		
Week 10 chg	125	125 -3.2 (2.40)	-3.00 (0.19)	122	122 -3.7 (2.29)	-3.82 (0.19)	-0.82 (-1.34, -0.30) 0.002 [-0.35 (-0.60, -0.10)]
Week 11	128	128 3.6 (2.46)		126	126 2.6 (2.22)		
Week 11 chg	128	128 -3.3 (2.40)	-3.11 (0.19)	126	126 -3.8 (2.26)	-3.90 (0.19)	-0.78 (-1.31, -0.26) 0.003 [-0.34 (-0.58, -0.09)]
Week 12	123	123 3.5 (2.44)		121	121 2.5 (2.21)		
Week 12 chg	123	123 -3.4 (2.45)	-3.14 (0.19)	121	121 -3.8 (2.38)	-4.00 (0.19)	-0.86 (-1.38, -0.33) 0.001 [-0.36 (-0.61, -0.10)]
Week 13	116	116 3.4 (2.40)		120	120 2.3 (2.13)		
Week 13 chg	116	116 -3.6 (2.32)	-3.27 (0.19)	120	120 -3.9 (2.26)	-4.04 (0.19)	-0.77 (-1.30, -0.25) 0.004 [-0.34 (-0.59, -0.08)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14	123	3.3 (2.42)		123	2.4 (2.18)		
Week 14 chg	123	-3.5 (2.33)	-3.34 (0.19)	123	-3.9 (2.27)	-4.04 (0.19)	-0.70 (-1.22, -0.18) 0.009 [-0.30 (-0.56, -0.05)]
Week 15	123	3.3 (2.47)		123	2.4 (2.18)		
Week 15 chg	123	-3.7 (2.35)	-3.43 (0.19)	123	-3.9 (2.35)	-4.08 (0.19)	-0.65 (-1.17, -0.12) 0.015 [-0.28 (-0.53, -0.02)]
Week 16	121	3.2 (2.40)		122	2.5 (2.17)		
Week 16 chg	121	-3.7 (2.28)	-3.40 (0.19)	122	-3.9 (2.32)	-4.07 (0.19)	-0.67 (-1.20, -0.15) 0.012 [-0.29 (-0.55, -0.04)]
Week 17	121	3.4 (2.55)		121	2.4 (2.30)		
Week 17 chg	121	-3.6 (2.46)	-3.34 (0.19)	121	-4.0 (2.36)	-4.10 (0.19)	-0.76 (-1.28, -0.23) 0.005 [-0.31 (-0.57, -0.06)]
Week 18	120	3.4 (2.65)		123	2.3 (2.24)		
Week 18 chg	120	-3.6 (2.51)	-3.35 (0.19)	123	-4.0 (2.40)	-4.15 (0.19)	-0.79 (-1.31, -0.27) 0.003 [-0.32 (-0.58, -0.07)]
Week 19	119	3.3 (2.75)		117	2.2 (2.22)		
Week 19 chg	119	-3.7 (2.57)	-3.42 (0.19)	117	-4.1 (2.46)	-4.23 (0.19)	-0.81 (-1.33, -0.28) 0.003 [-0.32 (-0.58, -0.06)]
Week 20	120	3.4 (2.78)		118	2.2 (2.12)		
Week 20 chg	120	-3.6 (2.63)	-3.32 (0.19)	118	-4.1 (2.42)	-4.18 (0.19)	-0.87 (-1.39, -0.34) 0.001 [-0.34 (-0.60, -0.09)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 21	118	3.2 (2.67)		115	2.1 (2.04)			
Week 21 chg	118	-3.8 (2.62)	-3.49 (0.19)	115	-4.2 (2.37)	-4.32 (0.19)	-0.83 (-1.36, -0.30) [-0.33 (-0.59, -0.07)]	0.002
Week 22	120	3.3 (2.72)		116	2.0 (1.98)			
Week 22 chg	120	-3.7 (2.65)	-3.37 (0.19)	116	-4.3 (2.35)	-4.38 (0.19)	-1.00 (-1.53, -0.48) [-0.40 (-0.66, -0.14)]	<.001
Week 23	120	3.2 (2.64)		114	2.0 (2.02)			
Week 23 chg	120	-3.7 (2.56)	-3.45 (0.19)	114	-4.2 (2.44)	-4.35 (0.19)	-0.90 (-1.43, -0.37) [-0.36 (-0.62, -0.10)]	<.001
Week 24	120	3.2 (2.59)		112	2.0 (1.91)			
Week 24 chg	120	-3.8 (2.57)	-3.52 (0.19)	112	-4.2 (2.37)	-4.38 (0.19)	-0.86 (-1.39, -0.34) [-0.35 (-0.61, -0.09)]	0.001
Week 25	114	2.8 (2.49)		115	2.0 (1.97)			
Week 25 chg	114	-4.1 (2.53)	-3.71 (0.19)	115	-4.3 (2.44)	-4.41 (0.19)	-0.70 (-1.23, -0.17) [-0.28 (-0.54, -0.02)]	0.010
Week 26	112	2.9 (2.50)		118	2.1 (1.98)			
Week 26 chg	112	-4.0 (2.55)	-3.62 (0.19)	118	-4.2 (2.48)	-4.34 (0.19)	-0.72 (-1.25, -0.19) [-0.29 (-0.55, -0.03)]	0.008

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Test for treatment and subgroup interaction: 0.0220
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Table 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 6.8 (1.73)		33	33 6.1 (2.06)		
Week 1		35 5.4 (2.09)			33 5.2 (2.16)		
Week 1 chg		35 -1.3 (1.44)	-1.20 (0.34)		33 -0.9 (1.45)	-0.92 (0.35)	0.28 (-0.69, 1.25) 0.565 [0.20 (-0.28, 0.67)]
Week 2		36 4.9 (2.14)			32 4.5 (2.37)		
Week 2 chg		36 -1.8 (1.74)	-1.79 (0.34)		32 -1.6 (1.65)	-1.73 (0.35)	0.06 (-0.91, 1.03) 0.904 [0.04 (-0.44, 0.51)]
Week 3		35 4.2 (2.00)			31 3.9 (2.42)		
Week 3 chg		35 -2.6 (1.85)	-2.45 (0.34)		31 -2.2 (1.77)	-2.34 (0.35)	0.10 (-0.87, 1.08) 0.837 [0.06 (-0.43, 0.54)]
Week 4		34 4.1 (2.19)			32 3.6 (2.40)		
Week 4 chg		34 -2.5 (2.00)	-2.37 (0.34)		32 -2.4 (1.88)	-2.59 (0.35)	-0.22 (-1.19, 0.76) 0.658 [-0.11 (-0.60, 0.37)]
Week 5		35 4.0 (2.39)			33 3.3 (2.38)		
Week 5 chg		35 -2.8 (2.13)	-2.61 (0.34)		33 -2.8 (2.01)	-2.92 (0.35)	-0.31 (-1.28, 0.67) 0.534 [-0.15 (-0.62, 0.33)]
Week 6		34 4.0 (2.56)			32 3.1 (2.47)		
Week 6 chg		34 -2.7 (2.33)	-2.46 (0.34)		32 -3.0 (2.23)	-3.18 (0.35)	-0.71 (-1.69, 0.26) 0.150 [-0.31 (-0.80, 0.17)]
Week 7		34 3.6 (2.20)			32 3.2 (2.42)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 7 chg	34		-3.2 (2.22)	-2.88	(0.34)	32		-2.8 (2.26)	-3.10	(0.35)	-0.22 (-1.19, 0.76) 0.661 [-0.10 (-0.58, 0.39)]
Week 8	32		3.5 (2.28)			31		2.9 (2.36)			
Week 8 chg	32		-3.2 (2.16)	-2.86	(0.34)	31		-3.2 (2.07)	-3.32	(0.35)	-0.46 (-1.44, 0.52) 0.355 [-0.22 (-0.71, 0.28)]
Week 9	34		3.4 (2.26)			33		2.7 (2.30)			
Week 9 chg	34		-3.3 (2.19)	-3.06	(0.34)	33		-3.4 (2.16)	-3.52	(0.35)	-0.46 (-1.43, 0.51) 0.353 [-0.21 (-0.69, 0.27)]
Week 10	33		3.5 (2.15)			30		2.7 (2.36)			
Week 10 chg	33		-3.3 (2.08)	-3.09	(0.34)	30		-3.4 (2.24)	-3.63	(0.36)	-0.54 (-1.52, 0.44) 0.280 [-0.25 (-0.75, 0.25)]
Week 11	34		3.0 (1.95)			32		2.5 (2.30)			
Week 11 chg	34		-3.7 (1.97)	-3.43	(0.34)	32		-3.5 (2.30)	-3.77	(0.35)	-0.34 (-1.32, 0.64) 0.490 [-0.16 (-0.64, 0.32)]
Week 12	33		3.0 (2.09)			32		2.5 (2.21)			
Week 12 chg	33		-3.7 (2.02)	-3.44	(0.34)	32		-3.5 (2.25)	-3.79	(0.35)	-0.34 (-1.32, 0.63) 0.488 [-0.16 (-0.65, 0.33)]
Week 13	32		3.0 (1.98)			31		2.3 (2.13)			
Week 13 chg	32		-3.7 (1.90)	-3.54	(0.34)	31		-3.7 (2.15)	-3.93	(0.35)	-0.38 (-1.37, 0.60) 0.442 [-0.19 (-0.68, 0.31)]
Week 14	33		3.1 (1.96)			30		2.2 (2.23)			

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Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
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Table 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	33	-3.7 (1.84)	-3.60 (0.34)	30	-3.9 (2.12)	-3.97 (0.36)	-0.37 (-1.35, 0.62) [-0.18 (-0.68, 0.31)]	0.464
Week 15	33	2.8 (2.00)		31	2.1 (2.09)			
Week 15 chg	33	-4.0 (2.05)	-3.82 (0.34)	31	-4.0 (2.36)	-4.25 (0.35)	-0.44 (-1.42, 0.54) [-0.20 (-0.69, 0.29)]	0.380
Week 16	32	2.9 (2.18)		31	2.2 (1.99)			
Week 16 chg	32	-3.8 (2.16)	-3.73 (0.34)	31	-4.0 (2.36)	-4.22 (0.35)	-0.49 (-1.47, 0.49) [-0.22 (-0.71, 0.28)]	0.326
Week 17	32	3.0 (2.27)		30	2.1 (2.05)			
Week 17 chg	32	-3.8 (2.28)	-3.74 (0.34)	30	-4.1 (2.20)	-4.27 (0.36)	-0.53 (-1.51, 0.46) [-0.24 (-0.74, 0.26)]	0.290
Week 18	32	3.1 (2.27)		30	2.0 (2.07)			
Week 18 chg	32	-3.7 (2.26)	-3.63 (0.34)	30	-4.2 (2.36)	-4.31 (0.36)	-0.68 (-1.67, 0.30) [-0.30 (-0.80, 0.20)]	0.172
Week 19	32	2.8 (2.35)		30	1.9 (1.91)			
Week 19 chg	32	-4.0 (2.36)	-3.90 (0.34)	30	-4.3 (2.21)	-4.42 (0.36)	-0.52 (-1.51, 0.46) [-0.23 (-0.73, 0.27)]	0.297
Week 20	32	3.0 (2.59)		30	2.0 (2.04)			
Week 20 chg	32	-3.9 (2.65)	-3.76 (0.34)	30	-4.2 (2.31)	-4.34 (0.36)	-0.59 (-1.57, 0.40) [-0.23 (-0.73, 0.26)]	0.242
Week 21	31	2.8 (2.41)		30	1.9 (2.10)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
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Table 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 21 chg	31	-4.0 (2.51)	-3.89 (0.34)	30	-4.3 (2.32)	-4.48 (0.36)	-0.58 (-1.57, 0.40) 0.244 [-0.24 (-0.75, 0.26)]
Week 22	32	3.0 (2.61)		31	2.0 (2.03)		
Week 22 chg	32	-3.8 (2.62)	-3.73 (0.34)	31	-4.3 (2.27)	-4.33 (0.35)	-0.60 (-1.58, 0.38) 0.228 [-0.25 (-0.74, 0.25)]
Week 23	32	2.8 (2.43)		30	1.9 (1.93)		
Week 23 chg	32	-4.0 (2.35)	-3.92 (0.34)	30	-4.3 (2.15)	-4.41 (0.36)	-0.48 (-1.47, 0.50) 0.334 [-0.21 (-0.71, 0.28)]
Week 24	32	2.7 (2.30)		30	2.0 (1.92)		
Week 24 chg	32	-4.2 (2.38)	-4.04 (0.34)	30	-4.2 (2.17)	-4.37 (0.36)	-0.33 (-1.32, 0.65) 0.508 [-0.14 (-0.64, 0.35)]
Week 25	30	2.1 (1.92)		30	1.9 (2.03)		
Week 25 chg	30	-4.6 (2.17)	-4.42 (0.35)	30	-4.4 (2.27)	-4.35 (0.36)	0.08 (-0.91, 1.06) 0.879 [0.03 (-0.47, 0.54)]
Week 26	30	2.4 (2.12)		31	2.1 (1.93)		
Week 26 chg	30	-4.3 (2.34)	-4.20 (0.35)	31	-4.1 (2.22)	-4.17 (0.35)	0.02 (-0.96, 1.01) 0.963 [0.01 (-0.49, 0.51)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA										
Baseline	101	100	7.0 (1.62)		105	104	6.4 (2.13)			
Week 1		100	5.9 (1.98)			103	5.2 (2.24)			
Week 1 chg		100	-1.0 (1.52)	-1.00 (0.22)		103	-1.2 (1.45)	-1.21 (0.22)	-0.21 (-0.83, 0.40) [-0.14 (-0.42, 0.13)]	0.490
Week 2		98	5.3 (2.35)			100	4.6 (2.49)			
Week 2 chg		98	-1.7 (2.07)	-1.63 (0.22)		100	-1.8 (1.85)	-1.88 (0.22)	-0.25 (-0.86, 0.37) [-0.13 (-0.40, 0.15)]	0.431
Week 3		98	4.8 (2.46)			100	3.9 (2.34)			
Week 3 chg		98	-2.1 (2.27)	-2.01 (0.22)		100	-2.5 (2.08)	-2.53 (0.22)	-0.52 (-1.13, 0.10) [-0.24 (-0.52, 0.04)]	0.098
Week 4		96	4.6 (2.57)			101	3.6 (2.39)			
Week 4 chg		96	-2.4 (2.31)	-2.21 (0.22)		101	-2.8 (2.12)	-2.85 (0.22)	-0.64 (-1.25, -0.02) [-0.29 (-0.57, -0.01)]	0.042
Week 5		96	4.3 (2.61)			96	3.3 (2.45)			
Week 5 chg		96	-2.7 (2.46)	-2.53 (0.22)		96	-3.1 (2.22)	-3.19 (0.22)	-0.67 (-1.28, -0.05) [-0.29 (-0.57, -0.00)]	0.034
Week 6		96	4.3 (2.52)			97	3.3 (2.42)			
Week 6 chg		96	-2.7 (2.38)	-2.51 (0.22)		97	-3.1 (2.25)	-3.21 (0.22)	-0.69 (-1.31, -0.08) [-0.30 (-0.58, -0.02)]	0.027
Week 7		95	4.0 (2.51)			96	3.0 (2.36)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 7 chg	95	-2.9 (2.45)	-2.74 (0.22)	96	-3.5 (2.27)	-3.51 (0.22)	-0.77 (-1.39, -0.15) [-0.33 (-0.61, -0.04)]	0.014
Week 8	95	4.1 (2.52)		94	2.8 (2.28)			
Week 8 chg	95	-2.9 (2.38)	-2.71 (0.22)	94	-3.7 (2.32)	-3.75 (0.22)	-1.04 (-1.66, -0.42) [-0.44 (-0.73, -0.15)]	0.001
Week 9	93	4.0 (2.56)		94	2.6 (2.20)			
Week 9 chg	93	-3.0 (2.39)	-2.83 (0.22)	94	-3.8 (2.26)	-3.94 (0.22)	-1.10 (-1.72, -0.48) [-0.47 (-0.77, -0.18)]	<.001
Week 10	92	3.8 (2.67)		92	2.7 (2.29)			
Week 10 chg	92	-3.2 (2.52)	-2.97 (0.22)	92	-3.8 (2.32)	-3.87 (0.22)	-0.91 (-1.52, -0.29) [-0.37 (-0.67, -0.08)]	0.004
Week 11	94	3.8 (2.60)		94	2.6 (2.20)			
Week 11 chg	94	-3.2 (2.52)	-3.00 (0.22)	94	-3.8 (2.25)	-3.93 (0.22)	-0.93 (-1.55, -0.31) [-0.39 (-0.68, -0.10)]	0.003
Week 12	90	3.7 (2.55)		89	2.5 (2.23)			
Week 12 chg	90	-3.3 (2.59)	-3.04 (0.22)	89	-3.9 (2.42)	-4.07 (0.22)	-1.03 (-1.65, -0.41) [-0.41 (-0.71, -0.11)]	0.001
Week 13	84	3.5 (2.54)		89	2.3 (2.14)			
Week 13 chg	84	-3.5 (2.47)	-3.18 (0.23)	89	-4.0 (2.31)	-4.08 (0.22)	-0.90 (-1.52, -0.28) [-0.38 (-0.68, -0.08)]	0.005
Week 14	90	3.5 (2.57)		93	2.4 (2.18)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	90	90	-3.5 (2.50)	-3.25	(0.22)	93	93	-3.9 (2.33)	-4.05	(0.22)	-0.81 (-1.43, -0.18) 0.011 [-0.33 (-0.63, -0.04)]
Week 15	90	90	3.5 (2.61)			92	92	2.5 (2.21)			
Week 15 chg	90	90	-3.6 (2.46)	-3.30	(0.22)	92	92	-3.9 (2.36)	-4.02	(0.22)	-0.72 (-1.34, -0.10) 0.023 [-0.30 (-0.59, -0.01)]
Week 16	89	89	3.4 (2.47)			91	91	2.5 (2.23)			
Week 16 chg	89	89	-3.6 (2.33)	-3.28	(0.22)	91	91	-3.9 (2.32)	-4.01	(0.22)	-0.73 (-1.35, -0.11) 0.021 [-0.32 (-0.61, -0.02)]
Week 17	89	89	3.5 (2.64)			91	91	2.5 (2.37)			
Week 17 chg	89	89	-3.5 (2.53)	-3.20	(0.22)	91	91	-3.9 (2.42)	-4.04	(0.22)	-0.84 (-1.46, -0.21) 0.009 [-0.34 (-0.63, -0.04)]
Week 18	88	88	3.5 (2.78)			93	93	2.4 (2.29)			
Week 18 chg	88	88	-3.6 (2.60)	-3.26	(0.22)	93	93	-4.0 (2.43)	-4.09	(0.22)	-0.83 (-1.45, -0.20) 0.009 [-0.33 (-0.62, -0.04)]
Week 19	87	87	3.5 (2.87)			87	87	2.3 (2.32)			
Week 19 chg	87	87	-3.6 (2.65)	-3.25	(0.22)	87	87	-4.0 (2.55)	-4.15	(0.22)	-0.90 (-1.53, -0.28) 0.005 [-0.35 (-0.65, -0.05)]
Week 20	88	88	3.6 (2.84)			88	88	2.2 (2.15)			
Week 20 chg	88	88	-3.5 (2.63)	-3.16	(0.22)	88	88	-4.0 (2.47)	-4.12	(0.22)	-0.96 (-1.58, -0.33) 0.003 [-0.38 (-0.67, -0.08)]
Week 21	87	87	3.3 (2.76)			85	85	2.2 (2.02)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.418.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 21 chg	87	-3.7 (2.67)	-3.35 (0.22)	85	-4.2 (2.40)	-4.26 (0.22)	-0.91 (-1.53, -0.28) [-0.36 (-0.66, -0.06)]	0.004
Week 22	88	3.5 (2.77)		85	2.0 (1.97)			
Week 22 chg	88	-3.6 (2.68)	-3.25 (0.22)	85	-4.3 (2.39)	-4.39 (0.22)	-1.14 (-1.76, -0.51) [-0.45 (-0.75, -0.15)]	<.001
Week 23	88	3.4 (2.71)		84	2.1 (2.06)			
Week 23 chg	88	-3.6 (2.64)	-3.29 (0.22)	84	-4.2 (2.55)	-4.33 (0.22)	-1.04 (-1.66, -0.41) [-0.40 (-0.70, -0.10)]	0.001
Week 24	88	3.4 (2.67)		82	2.0 (1.91)			
Week 24 chg	88	-3.7 (2.64)	-3.34 (0.22)	82	-4.3 (2.46)	-4.38 (0.22)	-1.05 (-1.67, -0.42) [-0.41 (-0.71, -0.11)]	0.001
Week 25	84	3.1 (2.63)		85	2.0 (1.97)			
Week 25 chg	84	-3.9 (2.64)	-3.45 (0.23)	85	-4.2 (2.51)	-4.42 (0.22)	-0.97 (-1.60, -0.34) [-0.38 (-0.68, -0.07)]	0.003
Week 26	82	3.1 (2.61)		87	2.1 (2.01)			
Week 26 chg	82	-3.9 (2.63)	-3.42 (0.23)	87	-4.2 (2.58)	-4.40 (0.22)	-0.98 (-1.60, -0.35) [-0.38 (-0.68, -0.07)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0220
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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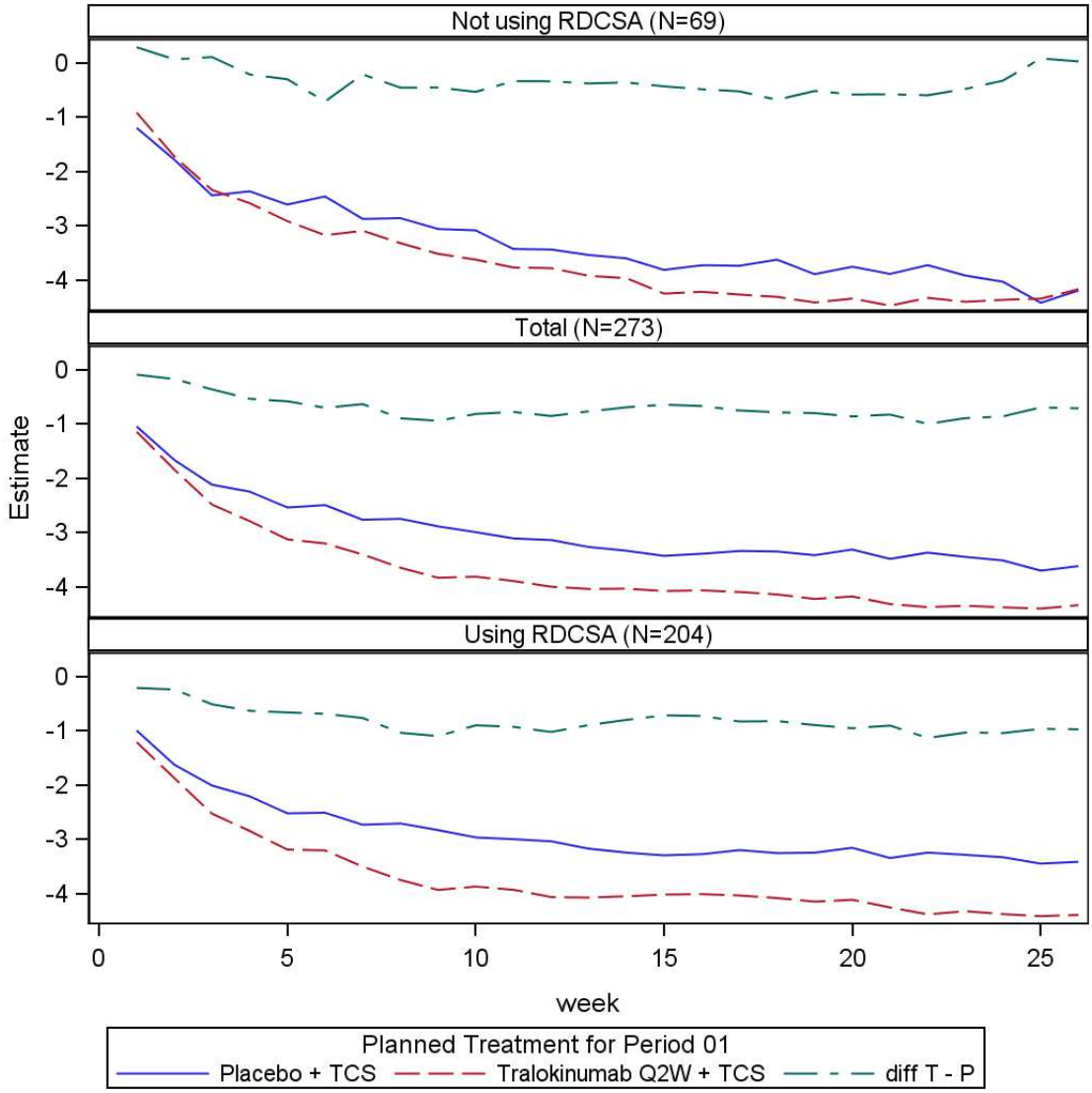
Figure 1.17.418.4.2: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.17.420.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 2		137 53.4 (17.62)			138 49.3 (18.19)		
Week 2 chg		137 -17.5 (16.06)	-17.24 (1.50)		138 -20.9 (16.72)	-21.09 (1.49)	-3.85 (-8.01, 0.31) 0.070 [-0.23 (-0.47, 0.00)]
Week 4		134 43.8 (18.34)			137 39.1 (17.64)		
Week 4 chg		134 -26.9 (18.44)	-26.30 (1.51)		137 -30.8 (17.25)	-31.04 (1.50)	-4.74 (-8.92, -0.57) 0.026 [-0.27 (-0.50, -0.03)]
Week 6		132 43.4 (18.92)			134 35.8 (16.64)		
Week 6 chg		132 -27.4 (19.15)	-26.83 (1.51)		134 -34.3 (17.49)	-34.46 (1.50)	-7.63 (-11.8, -3.43) <.001 [-0.42 (-0.66, -0.17)]
Week 8		133 41.6 (20.09)			130 33.4 (16.98)		
Week 8 chg		133 -29.1 (19.89)	-28.66 (1.51)		130 -36.6 (18.48)	-36.77 (1.51)	-8.11 (-12.3, -3.91) <.001 [-0.42 (-0.67, -0.18)]
Week 10		131 39.3 (19.95)			130 31.4 (18.19)		
Week 10 chg		131 -31.5 (21.12)	-30.81 (1.51)		130 -38.5 (19.49)	-38.57 (1.51)	-7.76 (-12.0, -3.55) <.001 [-0.38 (-0.63, -0.14)]
Week 12		128 38.6 (18.22)			128 30.5 (17.66)		
Week 12 chg		128 -32.5 (19.64)	-31.59 (1.52)		128 -39.5 (18.74)	-39.57 (1.52)	-7.98 (-12.2, -3.76) <.001 [-0.42 (-0.66, -0.17)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2260
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.420.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14		126 36.0 (19.61)			127 28.3 (17.87)		
Week 14 chg		126 -34.8 (20.31)	-34.25 (1.53)		127 -41.8 (20.11)	-41.39 (1.52)	-7.14 (-11.4, -2.91) <.001 [-0.35 (-0.60, -0.11)]
Week 16		124 36.3 (18.78)			123 27.0 (16.90)		
Week 16 chg		124 -34.7 (19.94)	-33.90 (1.53)		123 -43.3 (19.46)	-42.70 (1.53)	-8.80 (-13.0, -4.55) <.001 [-0.45 (-0.70, -0.19)]
Week 18		116 36.8 (19.98)			115 25.1 (15.97)		
Week 18 chg		116 -34.1 (20.70)	-33.27 (1.55)		115 -44.8 (19.27)	-43.62 (1.55)	-10.36 (-14.7, -6.05) <.001 [-0.52 (-0.78, -0.26)]
Week 20		107 35.7 (19.63)			117 25.6 (16.83)		
Week 20 chg		107 -35.6 (20.01)	-34.07 (1.57)		117 -44.9 (18.80)	-43.48 (1.54)	-9.41 (-13.7, -5.08) <.001 [-0.49 (-0.75, -0.22)]
Week 22		112 35.6 (20.27)			114 23.3 (14.77)		
Week 22 chg		112 -35.5 (20.64)	-34.08 (1.56)		114 -46.8 (19.03)	-45.23 (1.55)	-11.15 (-15.5, -6.83) <.001 [-0.56 (-0.83, -0.30)]
Week 24		112 34.6 (19.86)			117 23.3 (15.61)		
Week 24 chg		112 -36.5 (20.30)	-34.56 (1.56)		117 -46.9 (18.55)	-45.65 (1.54)	-11.09 (-15.4, -6.78) <.001 [-0.57 (-0.84, -0.31)]
Week 26		118 33.1 (18.32)			125 23.8 (16.51)		
Week 26 chg		118 -38.1 (19.21)	-36.22 (1.54)		125 -46.3 (19.60)	-45.94 (1.52)	-9.72 (-14.0, -5.46) <.001 [-0.50 (-0.76, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2260
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.420.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 70.1 (12.80)		33	33 68.7 (10.87)		
Week 2		36 52.8 (15.72)			33 43.1 (19.53)		
Week 2 chg		36 -17.3 (14.73)	-16.95 (2.98)		33 -25.6 (19.33)	-26.09 (3.12)	-9.14 (-17.7, -0.58) 0.036 [-0.53 (-1.02, -0.05)]
Week 4		35 41.4 (20.24)			33 36.9 (20.96)		
Week 4 chg		35 -28.9 (19.50)	-28.24 (3.01)		33 -31.8 (19.63)	-32.27 (3.12)	-4.02 (-12.6, 4.57) 0.356 [-0.21 (-0.68, 0.27)]
Week 6		34 42.5 (20.52)			33 28.6 (16.24)		
Week 6 chg		34 -28.3 (20.41)	-26.96 (3.03)		33 -40.0 (16.35)	-40.63 (3.12)	-13.67 (-22.3, -5.06) 0.002 [-0.74 (-1.23, -0.24)]
Week 8		35 37.6 (21.01)			33 28.2 (15.49)		
Week 8 chg		35 -32.7 (21.70)	-31.86 (3.01)		33 -40.4 (15.63)	-41.06 (3.12)	-9.21 (-17.8, -0.62) 0.036 [-0.48 (-0.97, -0.00)]
Week 10		35 34.8 (19.81)			33 25.2 (18.90)		
Week 10 chg		35 -35.5 (20.99)	-34.63 (3.01)		33 -43.5 (19.38)	-44.14 (3.12)	-9.51 (-18.1, -0.92) 0.030 [-0.47 (-0.95, 0.01)]
Week 12		34 34.2 (19.45)			33 26.9 (18.45)		
Week 12 chg		34 -36.3 (19.26)	-34.61 (3.03)		33 -41.8 (19.21)	-42.40 (3.12)	-7.80 (-16.4, 0.81) 0.076 [-0.41 (-0.89, 0.08)]
Week 14		33 32.0 (19.70)			33 23.3 (17.63)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2260
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.420.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	33	-37.7 (20.97)	-36.28 (3.04)	33	-45.4 (19.18)	-46.04 (3.12)	-9.76 (-18.4, -1.14) 0.027 [-0.49 (-0.98, 0.00)]
Week 16	32	28.2 (17.44)		31	21.6 (16.73)		
Week 16 chg	32	-42.1 (20.52)	-39.08 (3.06)	31	-47.9 (19.66)	-48.59 (3.16)	-9.51 (-18.2, -0.81) 0.032 [-0.47 (-0.97, 0.03)]
Week 18	30	29.6 (16.52)		31	19.2 (13.76)		
Week 18 chg	30	-40.5 (19.79)	-37.70 (3.10)	31	-49.8 (17.78)	-48.95 (3.16)	-11.24 (-20.0, -2.49) 0.012 [-0.60 (-1.11, -0.09)]
Week 20	27	29.0 (17.64)		30	20.4 (14.30)		
Week 20 chg	27	-40.9 (19.89)	-37.86 (3.17)	30	-48.1 (15.46)	-47.65 (3.18)	-9.80 (-18.7, -0.91) 0.031 [-0.55 (-1.08, -0.02)]
Week 22	27	28.6 (20.74)		28	18.3 (13.26)		
Week 22 chg	27	-41.7 (22.05)	-38.24 (3.17)	28	-50.3 (16.20)	-48.76 (3.22)	-10.51 (-19.5, -1.57) 0.022 [-0.54 (-1.08, -0.01)]
Week 24	27	28.6 (20.95)		29	17.4 (12.55)		
Week 24 chg	27	-41.6 (22.52)	-38.25 (3.17)	29	-51.3 (14.57)	-50.55 (3.20)	-12.31 (-21.2, -3.40) 0.007 [-0.65 (-1.19, -0.12)]
Week 26	31	25.9 (17.84)		31	19.4 (16.53)		
Week 26 chg	31	-44.8 (19.67)	-42.19 (3.08)	31	-49.4 (17.68)	-50.30 (3.16)	-8.12 (-16.9, 0.62) 0.068 [-0.43 (-0.94, 0.07)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2260
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.420.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA							
Baseline	101	101 71.1 (12.91)		105	105 70.7 (12.40)		
Week 2		101 53.6 (18.32)			105 51.3 (17.39)		
Week 2 chg		101 -17.5 (16.58)	-17.41 (1.74)		105 -19.4 (15.62)	-19.48 (1.70)	-2.06 (-6.85, 2.72) 0.397 [-0.13 (-0.40, 0.15)]
Week 4		99 44.7 (17.64)			104 39.9 (16.49)		
Week 4 chg		99 -26.1 (18.10)	-25.74 (1.75)		104 -30.5 (16.51)	-30.59 (1.71)	-4.85 (-9.65, -0.05) 0.048 [-0.28 (-0.56, -0.00)]
Week 6		98 43.7 (18.43)			101 38.1 (16.17)		
Week 6 chg		98 -27.1 (18.80)	-26.88 (1.75)		101 -32.4 (17.51)	-32.43 (1.72)	-5.55 (-10.4, -0.73) 0.024 [-0.31 (-0.59, -0.03)]
Week 8		98 43.0 (19.66)			97 35.1 (17.18)		
Week 8 chg		98 -27.7 (19.15)	-27.62 (1.75)		97 -35.3 (19.26)	-35.35 (1.73)	-7.73 (-12.6, -2.89) 0.002 [-0.40 (-0.69, -0.12)]
Week 10		96 40.9 (19.85)			97 33.5 (17.54)		
Week 10 chg		96 -30.1 (21.08)	-29.54 (1.76)		97 -36.8 (19.33)	-36.72 (1.73)	-7.18 (-12.0, -2.33) 0.004 [-0.36 (-0.64, -0.07)]
Week 12		94 40.2 (17.60)			95 31.7 (17.30)		
Week 12 chg		94 -31.1 (19.70)	-30.62 (1.76)		95 -38.7 (18.62)	-38.64 (1.74)	-8.03 (-12.9, -3.16) 0.001 [-0.42 (-0.71, -0.13)]
Week 14		93 37.4 (19.49)			94 30.0 (17.72)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2260
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.420.4.1: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 14 chg	93	-33.7 (20.09)	-33.61 (1.77)	94	-40.5 (20.38)	-39.84 (1.74)	-6.23 (-11.1, -1.35) 0.012 [-0.31 (-0.60, -0.02)]
Week 16	92	39.1 (18.49)		92	28.8 (16.65)		
Week 16 chg	92	-32.1 (19.18)	-32.15 (1.77)	92	-41.7 (19.24)	-40.73 (1.75)	-8.58 (-13.5, -3.69) <.001 [-0.45 (-0.74, -0.15)]
Week 18	86	39.3 (20.55)		84	27.2 (16.25)		
Week 18 chg	86	-31.9 (20.66)	-31.79 (1.79)	84	-42.9 (19.56)	-41.82 (1.78)	-10.03 (-15.0, -5.06) <.001 [-0.50 (-0.80, -0.19)]
Week 20	80	37.9 (19.85)		87	27.4 (17.34)		
Week 20 chg	80	-33.8 (19.85)	-32.85 (1.82)	87	-43.8 (19.78)	-42.10 (1.77)	-9.24 (-14.2, -4.26) <.001 [-0.47 (-0.77, -0.16)]
Week 22	85	37.9 (19.72)		86	25.0 (14.93)		
Week 22 chg	85	-33.5 (19.91)	-32.76 (1.80)	86	-45.7 (19.81)	-44.06 (1.77)	-11.30 (-16.3, -6.34) <.001 [-0.57 (-0.87, -0.26)]
Week 24	85	36.6 (19.23)		88	25.3 (16.08)		
Week 24 chg	85	-34.8 (19.40)	-33.37 (1.79)	88	-45.5 (19.55)	-44.03 (1.76)	-10.66 (-15.6, -5.71) <.001 [-0.55 (-0.85, -0.24)]
Week 26	87	35.7 (17.87)		94	25.2 (16.33)		
Week 26 chg	87	-35.7 (18.58)	-34.19 (1.79)	94	-45.3 (20.17)	-44.50 (1.74)	-10.31 (-15.2, -5.40) <.001 [-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: 0.2260
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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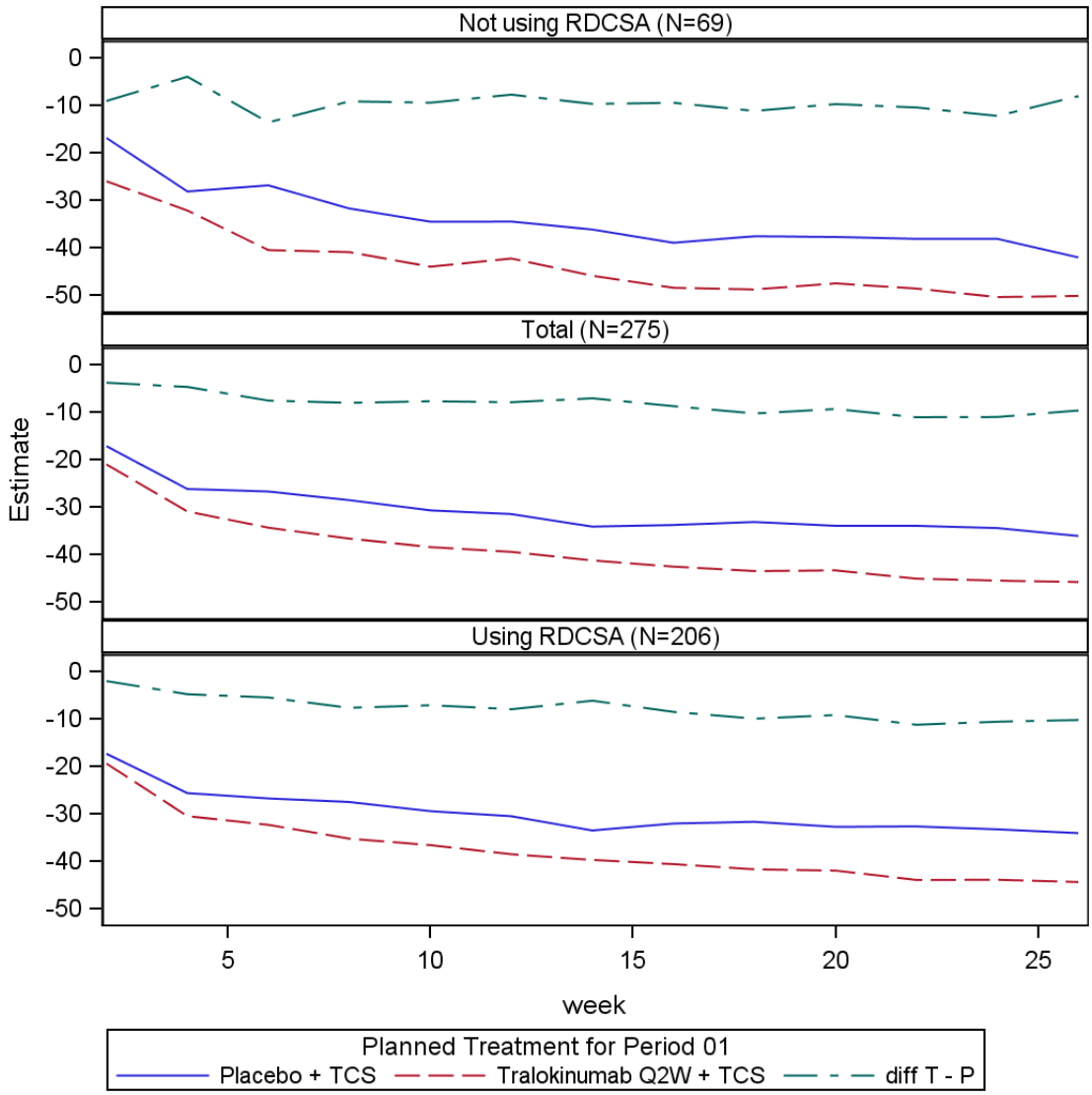
Figure 1.17.420.4.2: Total, RDSCA Use, change in SCORAD, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.17.422.4.1: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score											
Total											
Baseline	137	134	16.4 (6.33)			138	137	15.9 (6.53)			
Week 2		131	9.2 (6.47)				132	8.5 (6.17)			
Week 2 chg		131	-7.2 (5.73)	-7.13 (0.44)			132	-7.5 (5.92)	-7.54 (0.44)		-0.41 (-1.63, 0.81) 0.508 [-0.07 (-0.31, 0.17)]
Week 4		130	7.8 (6.27)				135	6.7 (5.98)			
Week 4 chg		130	-8.6 (6.67)	-8.30 (0.44)			135	-9.0 (6.32)	-9.13 (0.44)		-0.82 (-2.04, 0.40) 0.185 [-0.13 (-0.37, 0.11)]
Week 6		123	7.3 (6.07)				126	6.0 (5.79)			
Week 6 chg		123	-8.9 (7.23)	-8.60 (0.45)			126	-10.0 (6.75)	-9.85 (0.44)		-1.25 (-2.48, -0.01) 0.048 [-0.18 (-0.43, 0.07)]
Week 8		127	6.9 (5.70)				128	5.4 (5.11)			
Week 8 chg		127	-9.4 (6.84)	-8.94 (0.44)			128	-10.6 (6.29)	-10.36 (0.44)		-1.41 (-2.64, -0.19) 0.024 [-0.22 (-0.46, 0.03)]
Week 12		123	6.8 (5.89)				124	5.0 (3.92)			
Week 12 chg		123	-9.8 (7.26)	-9.29 (0.45)			124	-10.6 (5.77)	-10.55 (0.44)		-1.26 (-2.50, -0.02) 0.046 [-0.19 (-0.44, 0.06)]
Week 16		120	6.5 (5.63)				118	4.5 (3.88)			
Week 16 chg		120	-10.0 (6.54)	-9.68 (0.45)			118	-11.0 (5.99)	-11.14 (0.45)		-1.46 (-2.71, -0.22) 0.022 [-0.23 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5437
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.422.4.1: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	6.2 (5.67)		111	4.1 (3.92)			
Week 20 chg	102	-9.9 (7.06)	-9.64 (0.46)	111	-11.4 (5.58)	-11.49 (0.45)	-1.85 (-3.13, -0.57) [-0.29 (-0.56, -0.02)]	0.005
Week 26	110	6.3 (5.26)		116	4.3 (4.31)			
Week 26 chg	110	-10.4 (6.56)	-9.61 (0.46)	116	-11.1 (6.17)	-11.28 (0.45)	-1.67 (-2.93, -0.41) [-0.26 (-0.52, -0.00)]	0.010

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5437
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.422.4.1: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 15.8 (5.16)		33	33 15.7 (5.32)		
Week 2		35 8.5 (5.22)			32 9.1 (5.87)		
Week 2 chg		35 -6.9 (5.85)	-7.26 (0.73)		32 -6.7 (4.71)	-6.70 (0.77)	0.56 (-1.54, 2.65) 0.602 [0.10 (-0.38, 0.58)]
Week 4		34 6.9 (4.36)			33 7.0 (5.67)		
Week 4 chg		34 -9.1 (6.16)	-8.80 (0.74)		33 -8.7 (5.20)	-8.75 (0.76)	0.05 (-2.04, 2.15) 0.960 [0.01 (-0.47, 0.49)]
Week 6		33 6.9 (5.92)			31 5.7 (4.28)		
Week 6 chg		33 -8.6 (7.71)	-8.62 (0.75)		31 -10.1 (4.74)	-10.05 (0.77)	-1.43 (-3.56, 0.69) 0.185 [-0.22 (-0.71, 0.27)]
Week 8		35 5.9 (3.96)			33 5.7 (4.60)		
Week 8 chg		35 -9.9 (5.66)	-9.71 (0.74)		33 -10.0 (5.19)	-10.02 (0.76)	-0.31 (-2.40, 1.77) 0.766 [-0.06 (-0.53, 0.42)]
Week 12		31 5.6 (4.54)			33 5.8 (4.10)		
Week 12 chg		31 -10.3 (6.07)	-9.74 (0.76)		33 -9.9 (4.82)	-9.96 (0.76)	-0.22 (-2.35, 1.90) 0.836 [-0.04 (-0.53, 0.45)]
Week 16		31 4.7 (3.38)			30 5.5 (3.56)		
Week 16 chg		31 -11.2 (5.22)	-10.94 (0.76)		30 -10.3 (5.13)	-10.43 (0.78)	0.51 (-1.65, 2.67) 0.641 [0.10 (-0.40, 0.60)]
Week 20		26 5.5 (3.83)			28 5.0 (4.17)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5437
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.422.4.1: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	26	-9.9 (5.36)	-10.24 (0.81)	28	-10.5 (4.16)	-10.76 (0.80)	-0.52 (-2.76, 1.72) [-0.11 (-0.64, 0.43)]	0.649
Week 26	31	6.0 (4.52)		28	5.9 (5.24)			
Week 26 chg	31	-10.2 (6.22)	-9.76 (0.77)	28	-9.5 (5.30)	-9.92 (0.80)	-0.16 (-2.35, 2.02) [-0.03 (-0.54, 0.48)]	0.883

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5437
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.422.4.1: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	98 16.6 (6.72)		105	104 15.9 (6.89)			
Week 2		96 9.4 (6.88)			100 8.3 (6.28)			
Week 2 chg		96 -7.4 (5.71)	-7.09 (0.53)		100 -7.8 (6.25)	-7.81 (0.52)	-0.72 (-2.19, 0.74) [-0.12 (-0.40, 0.16)]	0.332
Week 4		96 8.1 (6.82)			102 6.7 (6.11)			
Week 4 chg		96 -8.4 (6.87)	-8.15 (0.53)		102 -9.1 (6.66)	-9.24 (0.52)	-1.09 (-2.55, 0.38) [-0.16 (-0.44, 0.12)]	0.145
Week 6		90 7.4 (6.16)			95 6.1 (6.22)			
Week 6 chg		90 -9.0 (7.09)	-8.64 (0.54)		95 -9.9 (7.31)	-9.77 (0.53)	-1.13 (-2.62, 0.35) [-0.16 (-0.45, 0.13)]	0.134
Week 8		92 7.3 (6.22)			95 5.3 (5.30)			
Week 8 chg		92 -9.1 (7.25)	-8.69 (0.54)		95 -10.8 (6.65)	-10.45 (0.53)	-1.76 (-3.24, -0.28) [-0.25 (-0.54, 0.03)]	0.020
Week 12		92 7.2 (6.26)			91 4.8 (3.85)			
Week 12 chg		92 -9.6 (7.64)	-9.16 (0.54)		91 -10.9 (6.08)	-10.74 (0.53)	-1.57 (-3.06, -0.08) [-0.23 (-0.52, 0.06)]	0.038
Week 16		89 7.1 (6.12)			88 4.1 (3.94)			
Week 16 chg		89 -9.5 (6.92)	-9.26 (0.54)		88 -11.2 (6.27)	-11.35 (0.53)	-2.09 (-3.59, -0.59) [-0.32 (-0.61, -0.02)]	0.006
Week 20		76 6.5 (6.18)			83 3.8 (3.80)			

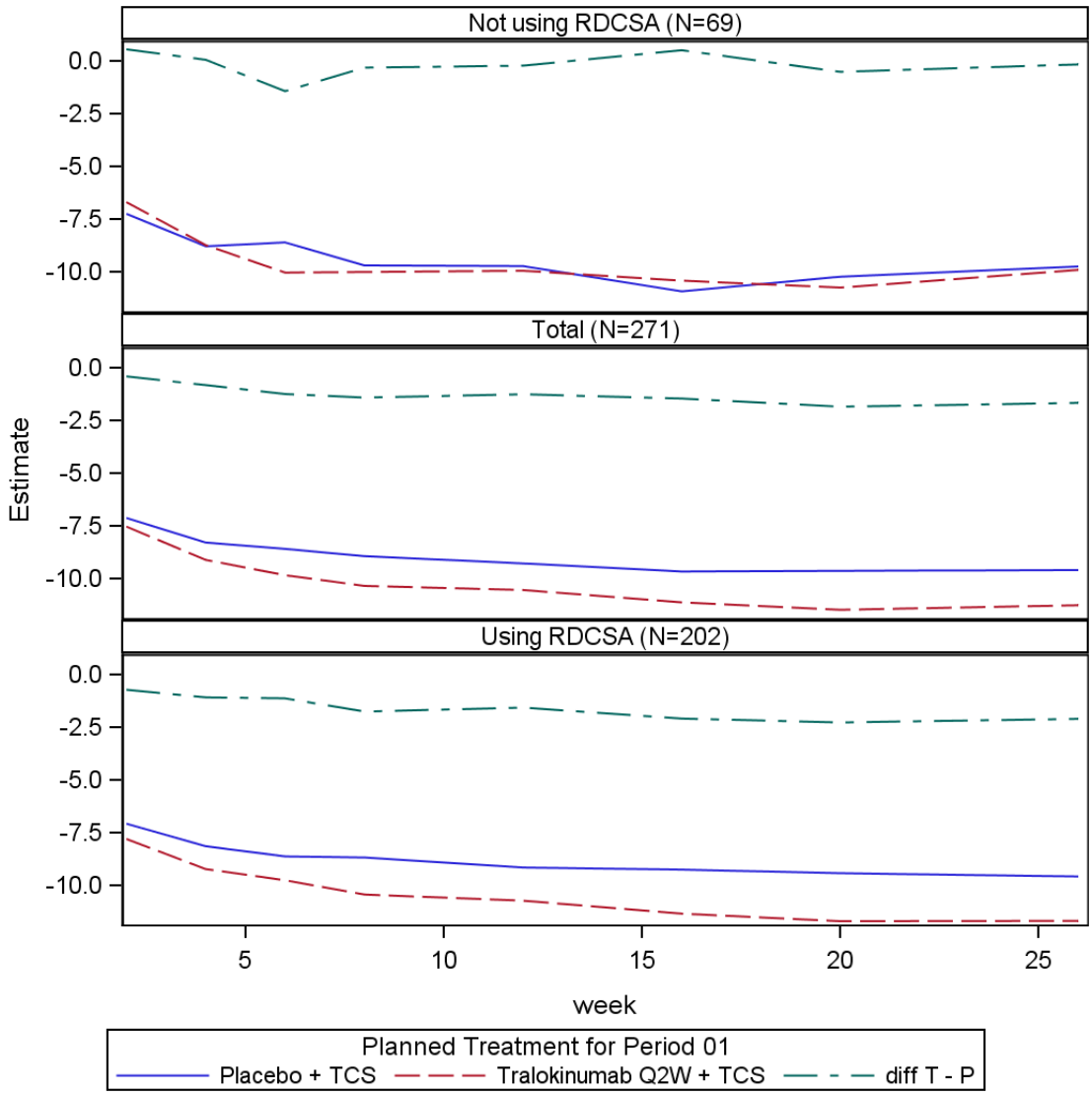
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5437
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.422.4.1: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20 chg	76	-9.9 (7.58)	-9.43 (0.56)	83	-11.7 (5.98)	-11.71 (0.54)	-2.28 (-3.80, -0.75) [-0.34 (-0.65, -0.02)]	0.004
Week 26	79	6.4 (5.55)		88	3.8 (3.87)			
Week 26 chg	79	-10.5 (6.73)	-9.59 (0.55)	88	-11.6 (6.36)	-11.70 (0.53)	-2.11 (-3.62, -0.59) [-0.32 (-0.63, -0.02)]	0.007

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5437
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.422.4.2: Total, RDSCA Use, change in DLQI, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.17.423.4.1: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total											
Total											
Baseline	137	134	20.9 (5.72)			138	135	21.3 (5.12)			
Week 2		130	15.1 (6.91)				130	13.5 (6.31)			
Week 2 chg		130	-5.9 (6.29)	-5.97	(0.55)		130	-7.7 (5.43)	-7.67	(0.55)	-1.71 (-3.23, -0.18) 0.029 [-0.29 (-0.53, -0.05)]
Week 4		130	13.8 (7.45)				133	11.6 (6.30)			
Week 4 chg		130	-7.1 (7.56)	-7.11	(0.55)		133	-9.7 (6.02)	-9.53	(0.55)	-2.42 (-3.94, -0.89) 0.002 [-0.35 (-0.60, -0.11)]
Week 6		123	13.5 (7.81)				124	10.9 (5.95)			
Week 6 chg		123	-7.2 (8.29)	-7.29	(0.56)		124	-10.6 (6.27)	-10.35	(0.56)	-3.07 (-4.61, -1.52) <.001 [-0.42 (-0.67, -0.17)]
Week 8		127	13.1 (7.02)				126	9.9 (5.79)			
Week 8 chg		127	-7.6 (7.95)	-7.70	(0.55)		126	-11.5 (6.10)	-11.16	(0.55)	-3.46 (-5.00, -1.92) <.001 [-0.49 (-0.74, -0.24)]
Week 12		123	13.0 (7.39)				122	9.2 (5.72)			
Week 12 chg		123	-8.0 (8.26)	-7.91	(0.56)		122	-12.4 (6.20)	-11.78	(0.56)	-3.88 (-5.43, -2.33) <.001 [-0.53 (-0.79, -0.28)]
Week 16		120	13.0 (7.69)				116	9.1 (5.58)			
Week 16 chg		120	-8.0 (8.09)	-8.08	(0.56)		116	-12.2 (6.39)	-11.81	(0.56)	-3.73 (-5.30, -2.17) <.001 [-0.51 (-0.77, -0.25)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9603
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.423.4.1: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 20	102	12.3 (7.64)		109	9.0 (5.60)			
Week 20 chg	102	-8.3 (7.60)	-8.25 (0.58)	109	-12.2 (6.08)	-11.90 (0.57)	-3.65 (-5.25, -2.05) [-0.53 (-0.81, -0.26)]	<.001
Week 26	110	11.8 (7.82)		114	8.2 (5.65)			
Week 26 chg	110	-8.9 (8.23)	-8.77 (0.57)	114	-12.8 (6.59)	-12.64 (0.57)	-3.86 (-5.44, -2.28) [-0.52 (-0.79, -0.25)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9603
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.423.4.1: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 19.9 (5.44)		33	32 21.5 (4.80)		
Week 2		35 14.6 (6.78)			31 13.9 (6.65)		
Week 2 chg		35 -5.2 (7.05)	-5.76 (1.10)		31 -7.6 (4.71)	-7.24 (1.17)	-1.48 (-4.68, 1.71) 0.360 [-0.24 (-0.73, 0.24)]
Week 4		34 12.9 (7.69)			32 12.5 (6.00)		
Week 4 chg		34 -7.1 (9.12)	-7.49 (1.11)		32 -9.0 (4.81)	-8.45 (1.16)	-0.96 (-4.15, 2.23) 0.554 [-0.13 (-0.61, 0.35)]
Week 6		33 13.5 (8.58)			30 11.4 (5.45)		
Week 6 chg		33 -6.1 (9.36)	-6.80 (1.12)		30 -10.3 (5.05)	-9.74 (1.18)	-2.94 (-6.19, 0.30) 0.075 [-0.39 (-0.88, 0.11)]
Week 8		35 11.8 (7.06)			32 10.7 (5.56)		
Week 8 chg		35 -8.0 (8.36)	-8.50 (1.10)		32 -10.8 (5.77)	-10.10 (1.16)	-1.60 (-4.78, 1.59) 0.323 [-0.22 (-0.70, 0.26)]
Week 12		31 11.6 (7.60)			32 9.8 (5.46)		
Week 12 chg		31 -8.1 (9.44)	-8.38 (1.14)		32 -11.7 (6.00)	-10.93 (1.16)	-2.55 (-5.78, 0.68) 0.122 [-0.32 (-0.82, 0.17)]
Week 16		31 11.3 (7.56)			29 9.8 (5.81)		
Week 16 chg		31 -8.5 (8.08)	-8.62 (1.14)		29 -12.0 (6.32)	-11.34 (1.19)	-2.71 (-6.00, 0.57) 0.104 [-0.37 (-0.88, 0.14)]
Week 20		26 11.4 (7.47)			27 10.1 (4.53)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9603
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.423.4.1: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 20 chg	26	-8.0 (7.51)	-9.14 (1.20)	27	-11.0 (4.88)	-10.65 (1.21)	-1.51 (-4.89, 1.87) 0.380 [-0.24 (-0.78, 0.30)]
Week 26	31	10.9 (8.26)		27	8.7 (5.67)		
Week 26 chg	31	-8.9 (8.89)	-8.96 (1.14)	27	-12.4 (5.57)	-12.35 (1.21)	-3.38 (-6.68, -0.09) 0.044 [-0.45 (-0.97, 0.07)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9603
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.423.4.1: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA							
Baseline	101	98 21.2 (5.81)		105	103 21.2 (5.24)		
Week 2		95 15.3 (6.99)			99 13.4 (6.23)		
Week 2 chg		95 -6.2 (6.00)	-6.04 (0.64)		99 -7.8 (5.65)	-7.79 (0.62)	-1.75 (-3.50, 0.01) 0.051 [-0.30 (-0.58, -0.02)]
Week 4		96 14.1 (7.39)			101 11.3 (6.40)		
Week 4 chg		96 -7.1 (6.98)	-7.01 (0.64)		101 -9.9 (6.37)	-9.83 (0.62)	-2.82 (-4.57, -1.07) 0.002 [-0.42 (-0.70, -0.14)]
Week 6		90 13.5 (7.55)			94 10.7 (6.12)		
Week 6 chg		90 -7.6 (7.87)	-7.48 (0.65)		94 -10.7 (6.63)	-10.54 (0.63)	-3.06 (-4.83, -1.28) <.001 [-0.42 (-0.71, -0.13)]
Week 8		92 13.6 (6.98)			94 9.6 (5.87)		
Week 8 chg		92 -7.4 (7.83)	-7.42 (0.64)		94 -11.8 (6.22)	-11.47 (0.63)	-4.05 (-5.82, -2.28) <.001 [-0.57 (-0.87, -0.28)]
Week 12		92 13.5 (7.30)			90 9.0 (5.83)		
Week 12 chg		92 -8.0 (7.88)	-7.81 (0.64)		90 -12.6 (6.29)	-12.01 (0.64)	-4.20 (-5.98, -2.42) <.001 [-0.59 (-0.89, -0.29)]
Week 16		89 13.5 (7.69)			87 8.8 (5.51)		
Week 16 chg		89 -7.8 (8.14)	-7.92 (0.65)		87 -12.3 (6.45)	-11.93 (0.64)	-4.00 (-5.79, -2.21) <.001 [-0.54 (-0.85, -0.24)]
Week 20		76 12.7 (7.72)			82 8.6 (5.89)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9603
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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.

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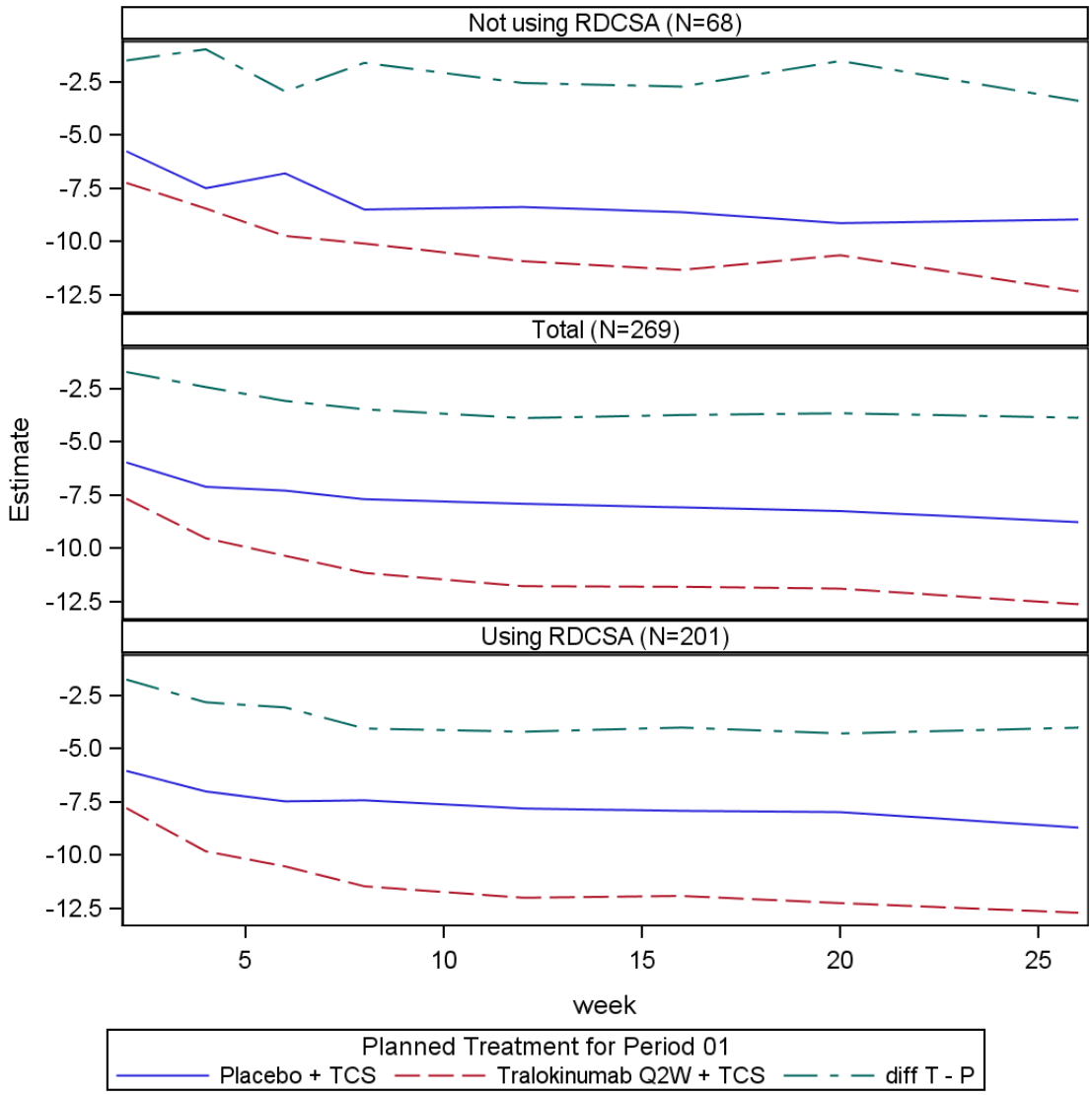
Table 1.17.423.4.1: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Week 20 chg	76	-8.4 (7.68)	-7.98 (0.67)	82	-12.6 (6.40)	-12.26 (0.65)	-4.28 (-6.12, -2.45) <.001 [-0.61 (-0.93, -0.29)]
Week 26	79	12.2 (7.67)		87	8.1 (5.67)		
Week 26 chg	79	-8.8 (8.01)	-8.71 (0.66)	87	-13.0 (6.89)	-12.72 (0.64)	-4.01 (-5.82, -2.19) <.001 [-0.54 (-0.85, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.9603
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + 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 Prior CSA use, 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 1.17.423.4.2: Total, RDSCA Use, change in POEM, Treatment policy, LP0162-1346, Week 26



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 Prior CSA use, 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 1.17.428.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 2		137 4.3 (2.75)			138 3.8 (2.71)		
Week 2 chg		137 -2.4 (2.99)	-2.41 (0.22)		138 -2.8 (2.87)	-2.87 (0.22)	-0.45 (-1.08, 0.17) 0.153 [-0.16 (-0.39, 0.08)]
Week 4		134 3.4 (2.75)			137 2.9 (2.68)		
Week 4 chg		134 -3.3 (3.29)	-3.23 (0.23)		137 -3.8 (2.99)	-3.80 (0.22)	-0.58 (-1.20, 0.05) 0.071 [-0.18 (-0.42, 0.06)]
Week 6		132 3.5 (2.88)			134 2.6 (2.58)		
Week 6 chg		132 -3.2 (3.30)	-3.15 (0.23)		134 -4.1 (2.81)	-4.07 (0.23)	-0.92 (-1.55, -0.29) 0.004 [-0.30 (-0.54, -0.06)]
Week 8		133 3.2 (2.69)			130 2.3 (2.47)		
Week 8 chg		133 -3.6 (3.29)	-3.50 (0.23)		130 -4.4 (2.91)	-4.34 (0.23)	-0.84 (-1.47, -0.21) 0.009 [-0.27 (-0.51, -0.03)]
Week 10		131 3.0 (2.78)			130 2.2 (2.56)		
Week 10 chg		131 -3.8 (3.38)	-3.65 (0.23)		130 -4.5 (2.93)	-4.46 (0.23)	-0.81 (-1.44, -0.18) 0.012 [-0.26 (-0.50, -0.01)]
Week 12		128 2.9 (2.68)			128 2.1 (2.48)		
Week 12 chg		128 -3.9 (3.37)	-3.73 (0.23)		128 -4.6 (2.96)	-4.55 (0.23)	-0.83 (-1.46, -0.19) 0.011 [-0.26 (-0.51, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3765
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.17.428.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	126	2.8 (2.94)		127	2.3 (2.60)			
Week 14 chg	126	-4.0 (3.48)	-3.88 (0.23)	127	-4.4 (3.07)	-4.33 (0.23)	-0.45 (-1.09, 0.18) [-0.14 (-0.38, 0.11)]	0.161
Week 16	124	2.7 (2.77)		123	1.9 (2.39)			
Week 16 chg	124	-4.1 (3.25)	-3.93 (0.23)	123	-4.7 (2.92)	-4.64 (0.23)	-0.72 (-1.36, -0.08) [-0.23 (-0.48, 0.02)]	0.027

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3765
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.17.428.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 6.7 (2.09)		33	33 6.6 (2.01)		
Week 2		36 4.0 (2.39)			33 3.6 (2.72)		
Week 2 chg		36 -2.6 (2.84)	-2.63 (0.40)		33 -3.0 (2.43)	-3.05 (0.42)	-0.42 (-1.56, 0.72) 0.469 [-0.16 (-0.63, 0.32)]
Week 4		35 3.1 (2.46)			33 2.9 (2.58)		
Week 4 chg		35 -3.6 (3.00)	-3.53 (0.40)		33 -3.7 (2.39)	-3.72 (0.42)	-0.19 (-1.33, 0.95) 0.744 [-0.07 (-0.55, 0.41)]
Week 6		34 3.7 (2.83)			33 2.2 (2.41)		
Week 6 chg		34 -2.9 (3.10)	-2.86 (0.41)		33 -4.4 (2.46)	-4.46 (0.42)	-1.60 (-2.75, -0.45) 0.007 [-0.57 (-1.06, -0.08)]
Week 8		35 2.8 (2.16)			33 1.9 (1.86)		
Week 8 chg		35 -3.9 (2.58)	-3.80 (0.40)		33 -4.8 (2.16)	-4.80 (0.42)	-1.00 (-2.14, 0.14) 0.086 [-0.42 (-0.90, 0.06)]
Week 10		35 2.6 (2.56)			33 2.2 (2.74)		
Week 10 chg		35 -4.1 (2.98)	-3.98 (0.40)		33 -4.4 (2.92)	-4.46 (0.42)	-0.47 (-1.62, 0.67) 0.416 [-0.16 (-0.64, 0.32)]
Week 12		34 2.5 (2.25)			33 2.1 (2.47)		
Week 12 chg		34 -4.1 (2.81)	-4.01 (0.41)		33 -4.6 (2.69)	-4.57 (0.42)	-0.56 (-1.71, 0.59) 0.335 [-0.20 (-0.68, 0.28)]
Week 14		33 2.2 (2.35)			33 2.0 (2.50)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3765
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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.

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Table 1.17.428.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	33	-4.6 (2.94)	-4.32 (0.41)	33	-4.7 (2.82)	-4.68 (0.42)	-0.36 (-1.52, 0.79) [-0.13 (-0.61, 0.36)]	0.535
Week 16	32	1.9 (2.08)		31	1.9 (2.43)			
Week 16 chg	32	-4.8 (2.70)	-4.59 (0.41)	31	-4.8 (2.80)	-4.84 (0.42)	-0.25 (-1.42, 0.91) [-0.09 (-0.59, 0.40)]	0.672

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3765
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.17.428.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	101 6.8 (2.26)		105	105 6.7 (2.47)			
Week 2		101 4.4 (2.87)			105 3.9 (2.72)			
Week 2 chg		101 -2.4 (3.05)	-2.34 (0.27)		105 -2.8 (3.00)	-2.81 (0.27)	-0.47 (-1.21, 0.28) [-0.15 (-0.43, 0.12)]	0.219
Week 4		99 3.5 (2.84)			104 2.8 (2.73)			
Week 4 chg		99 -3.2 (3.40)	-3.13 (0.27)		104 -3.8 (3.16)	-3.83 (0.27)	-0.70 (-1.45, 0.05) [-0.21 (-0.49, 0.06)]	0.067
Week 6		98 3.4 (2.91)			101 2.7 (2.63)			
Week 6 chg		98 -3.3 (3.38)	-3.25 (0.27)		101 -4.0 (2.92)	-3.94 (0.27)	-0.68 (-1.43, 0.07) [-0.22 (-0.50, 0.06)]	0.074
Week 8		98 3.3 (2.85)			97 2.4 (2.64)			
Week 8 chg		98 -3.5 (3.52)	-3.41 (0.27)		97 -4.3 (3.12)	-4.18 (0.27)	-0.78 (-1.53, -0.02) [-0.23 (-0.52, 0.05)]	0.043
Week 10		96 3.2 (2.85)			97 2.2 (2.51)			
Week 10 chg		96 -3.7 (3.52)	-3.54 (0.27)		97 -4.5 (2.95)	-4.46 (0.27)	-0.92 (-1.68, -0.17) [-0.28 (-0.57, -0.00)]	0.017
Week 12		94 3.1 (2.81)			95 2.1 (2.50)			
Week 12 chg		94 -3.8 (3.56)	-3.63 (0.27)		95 -4.6 (3.07)	-4.55 (0.27)	-0.91 (-1.67, -0.16) [-0.28 (-0.56, 0.01)]	0.018
Week 14		93 3.0 (3.11)			94 2.4 (2.63)			

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3765
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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.

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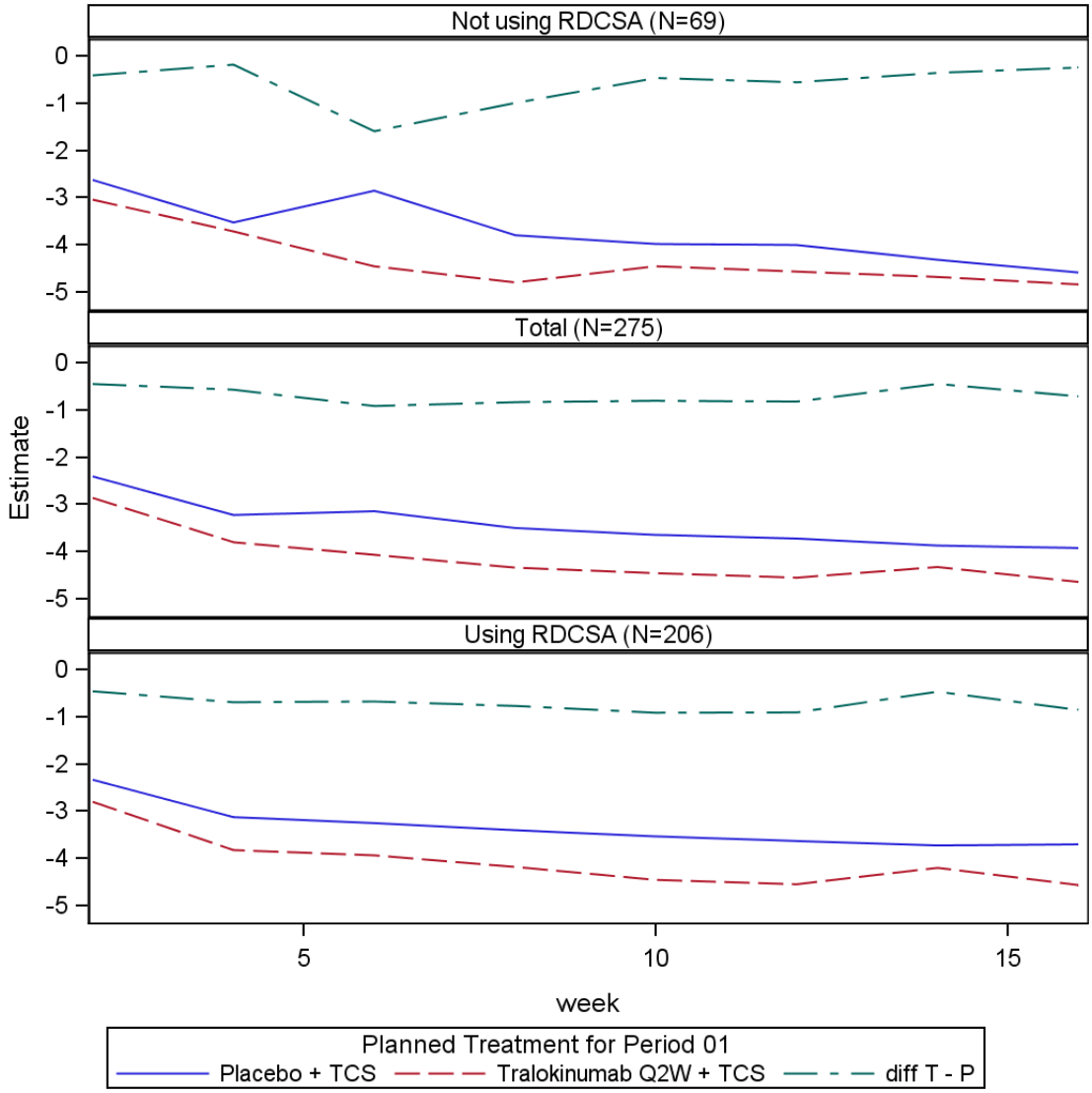
Table 1.17.428.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	93	-3.8 (3.65)	-3.73 (0.27)	94	-4.3 (3.16)	-4.20 (0.27)	-0.47 (-1.23, 0.28) [-0.14 (-0.43, 0.15)]	0.220
Week 16	92	3.0 (2.93)		92	2.0 (2.39)			
Week 16 chg	92	-3.8 (3.40)	-3.71 (0.28)	92	-4.6 (2.98)	-4.57 (0.27)	-0.86 (-1.62, -0.10) [-0.27 (-0.56, 0.02)]	0.027

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3765
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.17.428.4.2: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.17.429.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.80 (1.50)		133	17.3 (19.49)	18.41 (1.49)	2.61 (-1.55, 6.77) 0.219 [0.13 (-0.12, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.37 (1.51)		126	18.4 (21.17)	19.36 (1.51)	2.99 (-1.23, 7.20) 0.165 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.37 (1.53)		122	18.7 (21.48)	19.47 (1.53)	2.11 (-2.15, 6.37) 0.332 [0.09 (-0.16, 0.35)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.72 (1.54)		116	17.7 (22.49)	19.74 (1.55)	5.02 (0.71, 9.33) 0.022 [0.20 (-0.05, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3536
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.17.429.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 52.8 (21.28)		33	32 57.4 (18.26)		
Week 4		35 69.2 (18.51)			31 76.6 (13.60)		
Week 4 chg		35 17.2 (24.17)	15.66 (3.13)		31 19.7 (14.03)	20.81 (3.32)	5.15 (-3.91, 14.21) 0.263 [0.26 (-0.23, 0.74)]
Week 8		35 67.9 (21.80)			32 74.3 (16.14)		
Week 8 chg		35 14.5 (29.82)	12.78 (3.13)		32 16.9 (19.19)	18.93 (3.29)	6.15 (-2.86, 15.15) 0.179 [0.24 (-0.24, 0.72)]
Week 12		31 72.1 (20.14)			32 75.4 (14.44)		
Week 12 chg		31 18.7 (24.80)	18.42 (3.25)		32 18.0 (16.30)	19.63 (3.29)	1.22 (-7.96, 10.39) 0.794 [0.06 (-0.44, 0.55)]
Week 16		31 66.7 (24.94)			29 73.1 (19.96)		
Week 16 chg		31 14.0 (32.98)	11.89 (3.26)		29 16.4 (20.60)	18.10 (3.39)	6.21 (-3.10, 15.52) 0.189 [0.22 (-0.28, 0.73)]

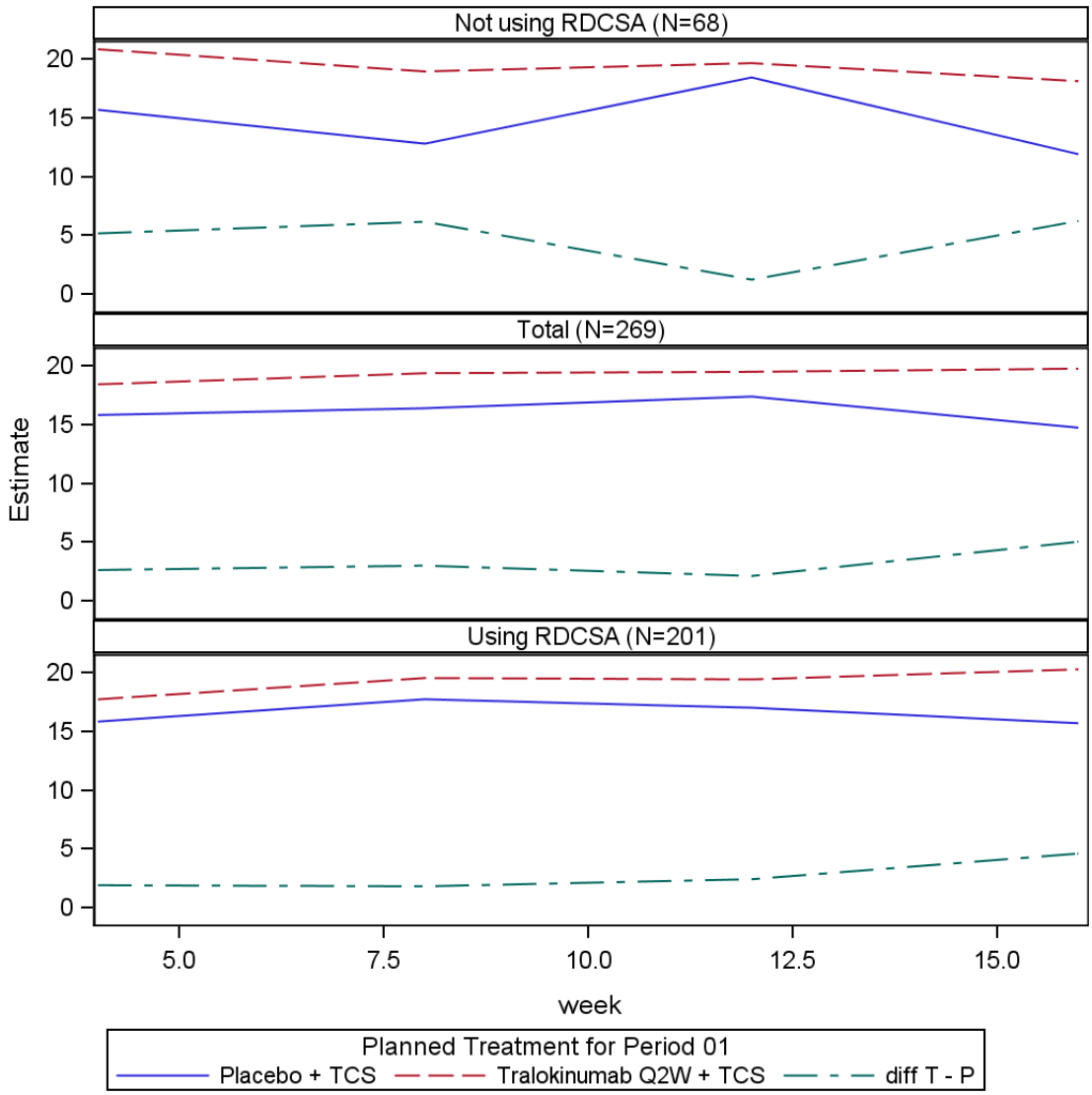
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3536
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.17.429.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA										
Baseline	101	98	52.4 (22.33)		105	103	56.3 (20.46)			
Week 4		96	69.8 (17.37)			102	72.9 (17.55)			
Week 4 chg		96	17.4 (21.07)	15.82 (1.71)		102	16.5 (20.88)	17.71 (1.66)	1.90 (-2.80, 6.60) [0.09 (-0.19, 0.37)]	0.428
Week 8		92	72.2 (17.41)			94	75.4 (16.35)			
Week 8 chg		92	19.7 (23.06)	17.72 (1.73)		94	19.0 (21.87)	19.52 (1.70)	1.81 (-2.98, 6.59) [0.08 (-0.21, 0.37)]	0.458
Week 12		92	70.9 (19.09)			90	75.4 (16.52)			
Week 12 chg		92	19.2 (22.51)	17.00 (1.73)		90	19.0 (23.12)	19.41 (1.72)	2.41 (-2.41, 7.23) [0.11 (-0.19, 0.40)]	0.326
Week 16		89	70.0 (20.72)			87	76.5 (15.94)			
Week 16 chg		89	17.6 (24.35)	15.68 (1.75)		87	18.1 (23.18)	20.26 (1.75)	4.59 (-0.29, 9.46) [0.19 (-0.10, 0.49)]	0.065

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3536
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.17.429.4.2: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, 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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.17.430.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EQ-5D-5L VAS Score									
Total									
Baseline	137	134	52.5 (21.97)		138	135	56.6 (19.90)		
Week 4		131	69.6 (17.61)			133	73.8 (16.74)		
Week 4 chg		131	17.3 (21.84)	15.83 (1.52)		133	17.3 (19.49)	18.45 (1.50)	2.62 (-1.59, 6.82) 0.222 [0.13 (-0.11, 0.37)]
Week 8		127	71.0 (18.73)			126	75.1 (16.24)		
Week 8 chg		127	18.2 (25.09)	16.39 (1.53)		126	18.4 (21.17)	19.38 (1.53)	2.99 (-1.26, 7.24) 0.168 [0.13 (-0.12, 0.38)]
Week 12		123	71.2 (19.28)			122	75.4 (15.94)		
Week 12 chg		123	19.1 (23.00)	17.49 (1.54)		122	18.7 (21.48)	19.49 (1.54)	1.99 (-2.30, 6.29) 0.362 [0.09 (-0.16, 0.34)]
Week 16		120	69.2 (21.82)			116	75.7 (17.01)		
Week 16 chg		120	16.7 (26.74)	14.83 (1.55)		116	17.7 (22.49)	19.65 (1.57)	4.82 (0.48, 9.16) 0.030 [0.19 (-0.06, 0.45)]
Week 20		103	72.7 (20.07)			108	77.3 (14.52)		
Week 20 chg		103	19.3 (25.56)	17.99 (1.61)		108	21.6 (20.57)	21.18 (1.59)	3.20 (-1.26, 7.65) 0.159 [0.14 (-0.13, 0.41)]
Week 26		113	72.4 (20.84)			116	76.4 (17.02)		
Week 26 chg		113	20.5 (25.83)	17.77 (1.58)		116	19.5 (21.18)	20.31 (1.56)	2.53 (-1.84, 6.90) 0.256 [0.11 (-0.15, 0.37)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2692
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.17.430.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA										
Baseline	36	36	52.8 (21.28)		33	32	57.4 (18.26)			
Week 4		35	69.2 (18.51)			31	76.6 (13.60)			
Week 4 chg		35	17.2 (24.17)	15.82 (3.11)		31	19.7 (14.03)	20.92 (3.30)	5.10 (-3.87, 14.08) [0.25 (-0.23, 0.74)]	0.263
Week 8		35	67.9 (21.80)			32	74.3 (16.14)			
Week 8 chg		35	14.5 (29.82)	12.91 (3.11)		32	16.9 (19.19)	19.06 (3.27)	6.15 (-2.78, 15.07) [0.24 (-0.24, 0.72)]	0.176
Week 12		31	72.1 (20.14)			32	75.4 (14.44)			
Week 12 chg		31	18.7 (24.80)	18.78 (3.23)		32	18.0 (16.30)	19.75 (3.27)	0.98 (-8.11, 10.07) [0.05 (-0.45, 0.54)]	0.832
Week 16		31	66.7 (24.94)			29	73.1 (19.96)			
Week 16 chg		31	14.0 (32.98)	12.40 (3.23)		29	16.4 (20.60)	18.18 (3.37)	5.78 (-3.46, 15.01) [0.21 (-0.30, 0.72)]	0.219
Week 20		26	68.8 (22.24)			27	78.5 (13.16)			
Week 20 chg		26	13.1 (29.28)	15.60 (3.42)		27	23.0 (17.94)	23.80 (3.44)	8.20 (-1.38, 17.78) [0.34 (-0.20, 0.88)]	0.093
Week 26		32	69.8 (21.64)			27	78.1 (12.74)			
Week 26 chg		32	17.0 (29.64)	14.58 (3.20)		27	23.7 (18.60)	24.01 (3.44)	9.44 (0.15, 18.72) [0.37 (-0.14, 0.89)]	0.046

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2692
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 1.17.430.4.1: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA										
Baseline	101	98	52.4 (22.33)		105	103	56.3 (20.46)			
Week 4		96	69.8 (17.37)			102	72.9 (17.55)			
Week 4 chg		96	17.4 (21.07)	15.82 (1.74)		102	16.5 (20.88)	17.72 (1.69)	1.90 (-2.88, 6.68) [0.09 (-0.19, 0.37)]	0.434
Week 8		92	72.2 (17.41)			94	75.4 (16.35)			
Week 8 chg		92	19.7 (23.06)	17.70 (1.76)		94	19.0 (21.87)	19.48 (1.73)	1.78 (-3.07, 6.63) [0.08 (-0.21, 0.37)]	0.471
Week 12		92	70.9 (19.09)			90	75.4 (16.52)			
Week 12 chg		92	19.2 (22.51)	17.04 (1.76)		90	19.0 (23.12)	19.37 (1.74)	2.33 (-2.55, 7.22) [0.10 (-0.19, 0.39)]	0.348
Week 16		89	70.0 (20.72)			87	76.5 (15.94)			
Week 16 chg		89	17.6 (24.35)	15.67 (1.77)		87	18.1 (23.18)	20.14 (1.76)	4.47 (-0.46, 9.40) [0.19 (-0.11, 0.48)]	0.075
Week 20		77	74.1 (19.26)			81	76.9 (15.00)			
Week 20 chg		77	21.3 (24.03)	18.82 (1.83)		81	21.1 (21.46)	20.25 (1.79)	1.42 (-3.61, 6.46) [0.06 (-0.25, 0.37)]	0.579
Week 26		81	73.5 (20.56)			89	75.9 (18.14)			
Week 26 chg		81	21.9 (24.23)	19.00 (1.81)		89	18.2 (21.83)	18.96 (1.75)	-0.03 (-5.00, 4.94) [-0.00 (-0.30, 0.30)]	0.989

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2692
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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.

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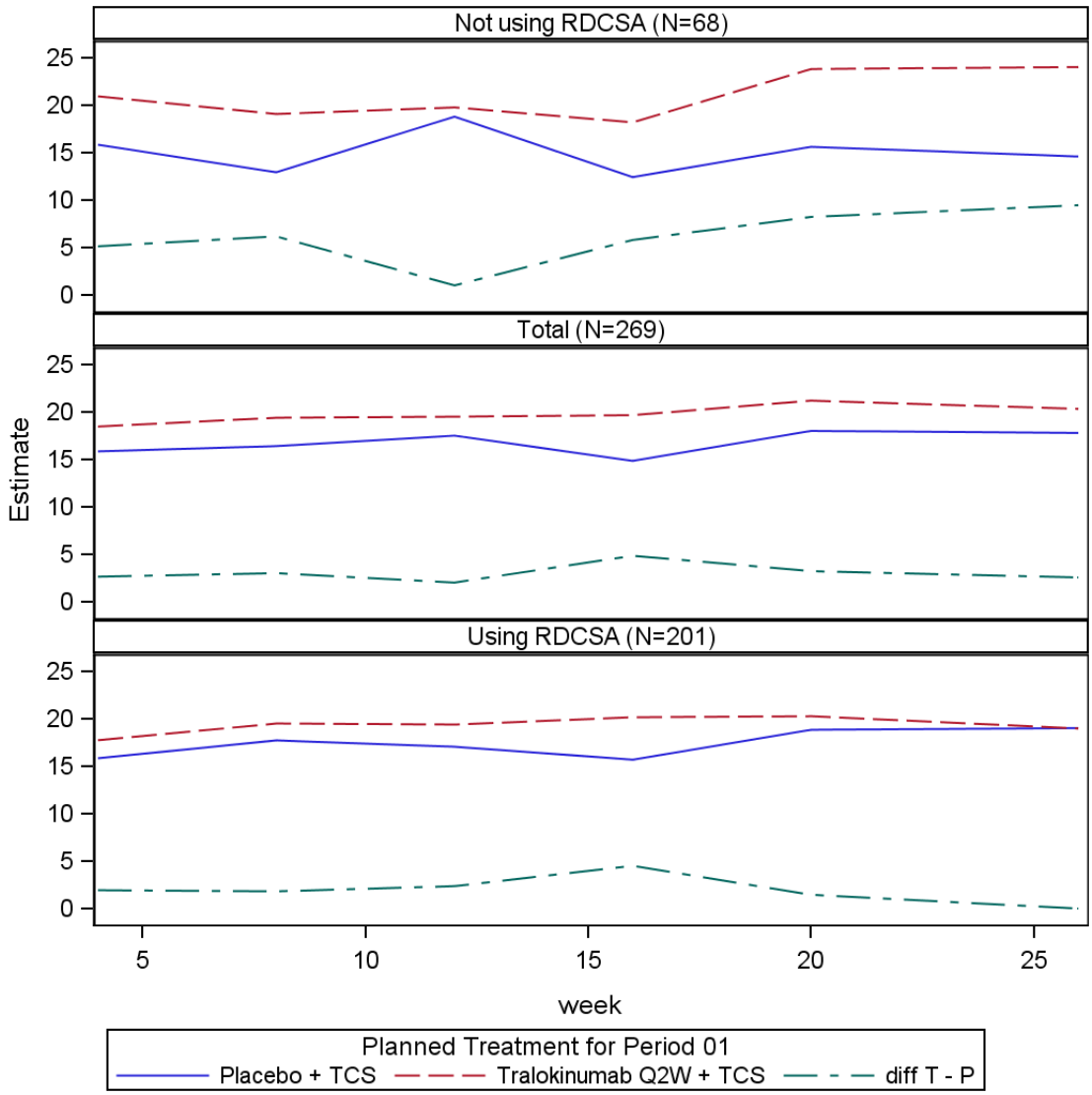
Figure 1.17.430.4.2: Total, RDSCA Use, change in EQ-5D-5L (VAS Component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 1.17.431.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Interference With Sleep (eDiary)							
Total							
Baseline	137	136 6.9 (1.64)		138	137 6.3 (2.11)		
Week 26		117 2.9 (2.55)			122 2.1 (2.00)		
Week 26 chg		116 -4.0 (2.53)	-3.74 (0.21)		121 -4.1 (2.47)	-4.34 (0.20)	-0.60 (-1.17, -0.03) 0.040 [-0.24 (-0.50, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4077
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.431.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 6.8 (1.73)		33	33 6.1 (2.06)		
Week 26		32 2.5 (2.24)			32 2.1 (1.91)		
Week 26 chg		32 -4.2 (2.29)	-4.03 (0.35)		32 -4.0 (2.24)	-4.21 (0.35)	-0.18 (-1.17, 0.82) 0.722 [-0.08 (-0.57, 0.41)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4077
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.431.4.1: Total, RDSCA Use, change in ECZEMA-related weekly Sleep NRS, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA												
Baseline	101	100	7.0 (1.62)			105	104	6.4 (2.13)				
Week 26		85	3.1 (2.65)				90	2.1 (2.04)				
Week 26 chg		84	-3.9 (2.62)	-3.64	(0.25)		89	-4.2 (2.56)	-4.40	(0.24)	-0.76 (-1.46, -0.06) [-0.29 (-0.59, 0.01)]	0.033

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4077
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 26 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.434.4.1: Total, RDSCA Use, SCORAD 90, Treatment policy estimand, LP0162-1346, Week 26

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 Q2W + TCS	138	21 (15.2)	11.7 (5.02;18.46)	4.3 (1.66;10.96)	5.0 (1.80;13.99)	0.0009	0.3704
Placebo + TCS	137	5 (3.6)					
Not using RDCSA							
Tralokinumab Q2W + TCS	33	7 (21.2)	13.0 (-3.56;29.50)	2.6 (0.73; 9.02)	3.0 (0.71;12.95)	0.1289	
Placebo + TCS	36	3 (8.3)					
Using RDCSA							
Tralokinumab Q2W + TCS	105	14 (13.3)	11.3 (4.26;18.40)	6.6 (1.56;28.03)	7.4 (1.65;33.47)	0.0025	
Placebo + TCS	101	2 (2.0)					

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. Treatment policy estimand: Missing values at Week 26 imputed as non-responders. Stratification for Prior CSA use and baseline IGA.

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Table 1.17.437.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Sleep Loss							
Total							
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)		
Week 26		121 2.5 (2.71)			127 1.6 (2.07)		
Week 26 chg		121 -4.4 (3.09)	-4.30 (0.21)		127 -5.0 (2.78)	-5.09 (0.21)	-0.78 (-1.37, -0.20) 0.009 [-0.27 (-0.52, -0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1873
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.437.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 6.7 (2.09)		33	33 6.6 (2.01)			
Week 26		32 1.6 (2.08)			31 1.5 (2.16)			
Week 26 chg		32 -5.1 (2.45)	-5.09 (0.36)		31 -5.2 (2.35)	-5.20 (0.36)	-0.12 (-1.13, 0.90) [-0.05 (-0.54, 0.45)]	0.821

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1873
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.437.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA											
Baseline	101	101	6.8 (2.26)			105	105	6.7 (2.47)			
Week 26		89	2.8 (2.86)				96	1.7 (2.04)			
Week 26 chg		89	-4.2 (3.27)	-4.02	(0.26)		96	-4.9 (2.92)	-5.04	(0.25)	-1.02 (-1.73, -0.31) 0.005 [-0.33 (-0.62, -0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1873
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data at week 16 is included as collected regardless of rescue medication or treatment discontinuation. Missing data are not imputed. Statistical model: value = Treatment + [Baseline value] + Prior CSA use + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.438.4.1: Total, RDSCA Use, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
SCORAD Score							
Total							
Baseline	137	137 70.8 (12.84)		138	138 70.2 (12.05)		
Week 26		121 33.4 (18.31)			127 24.1 (16.65)		
Week 26 chg		121 -37.9 (19.30)	-37.26 (1.53)		127 -45.9 (19.70)	-46.62 (1.50)	-9.36 (-13.6, -5.13) <.001 [-0.48 (-0.73, -0.23)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6241
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.438.4.1: Total, RDSCA Use, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 70.1 (12.80)		33	33 68.7 (10.87)		
Week 26		32 27.1 (18.82)			31 19.4 (16.53)		
Week 26 chg		32 -43.4 (20.88)	-42.42 (2.99)		31 -49.4 (17.68)	-50.27 (3.04)	-7.85 (-16.4, 0.70) 0.071 [-0.41 (-0.90, 0.09)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6241
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.438.4.1: Total, RDSCA Use, change in SCORAD, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	101 71.1 (12.91)		105	105 70.7 (12.40)			
Week 26		89 35.7 (17.68)			96 25.6 (16.48)			
Week 26 chg		89 -35.9 (18.42)	-35.45 (1.79)		96 -44.8 (20.26)	-45.35 (1.72)	-9.90 (-14.8, -5.00) [-0.51 (-0.80, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.6241
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.439.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Worst Pruritus (eDiary)							
Total							
Baseline	137	136 7.5 (1.37)		138	137 7.3 (1.45)		
Week 26		117 3.9 (2.53)			122 3.0 (1.94)		
Week 26 chg		116 -3.6 (2.55)	-3.47 (0.20)		121 -4.2 (2.13)	-4.31 (0.20)	-0.84 (-1.41, -0.28) 0.004 [-0.36 (-0.62, -0.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1264
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.439.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 7.4 (1.48)		33	33 7.0 (1.33)		
Week 26		32 3.5 (2.11)			32 3.2 (1.96)		
Week 26 chg		32 -3.9 (2.09)	-3.82 (0.33)		32 -3.8 (1.83)	-3.90 (0.33)	-0.08 (-1.03, 0.87) 0.865 [-0.04 (-0.53, 0.45)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1264
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.439.4.1: Total, RDSCA Use, change in Worst Daily Pruritus NRS (weekly average), ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA												
Baseline	101	100	7.5 (1.34)			105	104	7.3 (1.49)				
Week 26		85	4.1 (2.66)				90	2.9 (1.94)				
Week 26 chg		84	-3.4 (2.71)	-3.34	(0.25)		89	-4.4 (2.21)	-4.46	(0.24)	-1.12 (-1.81, -0.43) [-0.45 (-0.76, -0.15)]	0.002

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1264
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.440.4.1: Total, RDSCA Use, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
POEM Total							
Total							
Baseline	137	134 20.9 (5.72)		138	135 21.3 (5.12)		
Week 26		115 11.9 (7.89)			119 8.4 (5.90)		
Week 26 chg		113 -8.7 (8.23)	-8.90 (0.62)		116 -12.7 (6.64)	-12.63 (0.62)	-3.73 (-5.46, -2.00) <.001 [-0.50 (-0.76, -0.24)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7025
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.440.4.1: Total, RDSCA Use, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 19.9 (5.44)		33	32 21.5 (4.80)		
Week 26		32 11.4 (8.61)			28 9.0 (5.78)		
Week 26 chg		32 -8.5 (9.09)	-8.85 (1.22)		27 -12.4 (5.57)	-11.95 (1.33)	-3.10 (-6.73, 0.54) 0.094 [-0.40 (-0.92, 0.11)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7025
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.440.4.1: Total, RDSCA Use, change in POEM, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	98 21.2 (5.81)		105	103 21.2 (5.24)			
Week 26		83 12.1 (7.64)			91 8.2 (5.96)			
Week 26 chg		81 -8.8 (7.93)	-8.89 (0.73)		89 -12.9 (6.95)	-12.82 (0.69)	-3.93 (-5.91, -1.95) [-0.53 (-0.83, -0.22)]	<.001

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.7025
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.442.4.1: Total, RDSCA Use, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
DLQI Score							
Total							
Baseline	137	134 16.4 (6.33)		138	137 15.9 (6.53)		
Week 26		115 6.2 (5.20)			119 4.4 (4.42)		
Week 26 chg		113 -10.3 (6.57)	-10.01 (0.42)		118 -11.2 (6.17)	-11.51 (0.41)	-1.50 (-2.66, -0.34) 0.011 [-0.24 (-0.49, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1468
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.442.4.1: Total, RDSCA Use, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 15.8 (5.16)		33	33 15.7 (5.32)		
Week 26		32 6.1 (4.51)			28 5.9 (5.24)		
Week 26 chg		32 -9.9 (6.33)	-9.70 (0.80)		28 -9.5 (5.30)	-9.81 (0.85)	-0.12 (-2.46, 2.23) 0.922 [-0.02 (-0.53, 0.49)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1468
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.442.4.1: Total, RDSCA Use, change in DLQI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA							
Baseline	101	98 16.6 (6.72)		105	104 15.9 (6.89)		
Week 26		83 6.2 (5.47)			91 3.9 (4.05)		
Week 26 chg		81 -10.5 (6.69)	-10.06 (0.49)		90 -11.7 (6.36)	-12.06 (0.47)	-2.00 (-3.34, -0.66) 0.004 [-0.31 (-0.61, -0.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1468
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.443.4.1: Total, RDSCA Use, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 26		121 9.0 (10.05)			127 5.8 (7.95)		
Week 26 chg		121 -25.4 (13.63)	-24.33 (0.78)		127 -26.3 (12.87)	-27.34 (0.76)	-3.02 (-5.16, -0.87) 0.006 [-0.23 (-0.48, 0.02)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4312
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.443.4.1: Total, RDSCA Use, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 31.9 (13.21)		33	33 30.2 (8.24)		
Week 26		32 5.9 (8.47)			31 4.1 (8.39)		
Week 26 chg		32 -26.1 (12.70)	-25.08 (1.40)		31 -25.8 (11.84)	-26.83 (1.42)	-1.75 (-5.76, 2.26) 0.386 [-0.14 (-0.64, 0.35)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4312
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.443.4.1: Total, RDSCA Use, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA							
Baseline	101	101 34.5 (13.55)		105	105 32.7 (12.35)		
Week 26		89 10.2 (10.38)			96 6.3 (7.77)		
Week 26 chg		89 -25.1 (14.01)	-24.05 (0.93)		96 -26.4 (13.24)	-27.49 (0.90)	-3.44 (-5.99, -0.89) 0.009 [-0.25 (-0.54, 0.04)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4312
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.445.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Sleep Loss								
Total								
Baseline	137	137 6.7 (2.21)		138	138 6.7 (2.36)			
Week 2		137 4.3 (2.75)			138 3.8 (2.71)			
Week 2 chg		137 -2.4 (2.99)	-2.39 (0.22)		138 -2.8 (2.87)	-2.85 (0.22)	-0.46 (-1.07, 0.15)	0.140
							[-0.16 (-0.39, 0.08)]	
Week 4		134 3.4 (2.75)			137 2.9 (2.68)			
Week 4 chg		134 -3.3 (3.29)	-3.20 (0.22)		137 -3.8 (2.99)	-3.79 (0.22)	-0.58 (-1.20, 0.03)	0.062
							[-0.19 (-0.42, 0.05)]	
Week 6		132 3.5 (2.88)			134 2.6 (2.58)			
Week 6 chg		132 -3.2 (3.30)	-3.13 (0.22)		134 -4.1 (2.81)	-4.06 (0.22)	-0.93 (-1.54, -0.31)	0.003
							[-0.30 (-0.54, -0.06)]	
Week 8		133 3.2 (2.69)			130 2.3 (2.47)			
Week 8 chg		133 -3.6 (3.29)	-3.47 (0.22)		130 -4.4 (2.91)	-4.33 (0.22)	-0.85 (-1.47, -0.24)	0.007
							[-0.27 (-0.52, -0.03)]	
Week 10		131 3.0 (2.78)			130 2.2 (2.56)			
Week 10 chg		131 -3.8 (3.38)	-3.62 (0.22)		130 -4.5 (2.93)	-4.44 (0.22)	-0.82 (-1.43, -0.20)	0.009
							[-0.26 (-0.50, -0.01)]	
Week 12		128 2.9 (2.68)			128 2.1 (2.48)			
Week 12 chg		128 -3.9 (3.37)	-3.70 (0.22)		128 -4.6 (2.96)	-4.53 (0.22)	-0.83 (-1.45, -0.21)	0.008
							[-0.26 (-0.51, -0.02)]	

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0939
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.17.445.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14	126	2.8 (2.94)		127	2.3 (2.60)			
Week 14 chg	126	-4.0 (3.48)	-3.86 (0.22)	127	-4.4 (3.07)	-4.31 (0.22)	-0.45 (-1.07, 0.17) [-0.14 (-0.38, 0.11)]	0.156
Week 16	124	2.7 (2.77)		123	1.9 (2.39)			
Week 16 chg	124	-4.1 (3.25)	-3.91 (0.22)	123	-4.7 (2.92)	-4.63 (0.22)	-0.72 (-1.34, -0.10) [-0.23 (-0.48, 0.02)]	0.024
Week 18	116	2.9 (2.83)		115	1.7 (2.27)			
Week 18 chg	116	-3.9 (3.35)	-3.71 (0.23)	115	-4.8 (2.93)	-4.81 (0.23)	-1.10 (-1.73, -0.47) [-0.35 (-0.61, -0.09)]	<.001
Week 20	107	2.6 (2.71)		117	1.8 (2.37)			
Week 20 chg	107	-4.1 (3.17)	-3.95 (0.23)	117	-4.8 (2.97)	-4.78 (0.23)	-0.83 (-1.46, -0.20) [-0.27 (-0.53, -0.01)]	0.010
Week 22	112	2.5 (2.71)		114	1.5 (2.00)			
Week 22 chg	112	-4.2 (3.34)	-4.07 (0.23)	114	-5.0 (2.85)	-4.94 (0.23)	-0.87 (-1.51, -0.24) [-0.28 (-0.54, -0.02)]	0.007
Week 24	112	2.3 (2.55)		117	1.5 (2.05)			
Week 24 chg	112	-4.4 (3.18)	-4.21 (0.23)	117	-5.1 (2.80)	-4.96 (0.23)	-0.76 (-1.39, -0.12) [-0.25 (-0.51, 0.01)]	0.019
Week 26	118	2.4 (2.70)		125	1.6 (2.07)			
Week 26 chg	118	-4.4 (3.11)	-4.20 (0.23)	125	-5.0 (2.80)	-4.92 (0.22)	-0.72 (-1.35, -0.10) [-0.24 (-0.50, 0.01)]	0.024

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0939
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.17.445.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 6.7 (2.09)		33	33 6.6 (2.01)		
Week 2		36 4.0 (2.39)			33 3.6 (2.72)		
Week 2 chg		36 -2.6 (2.84)	-2.61 (0.38)		33 -3.0 (2.43)	-3.03 (0.39)	-0.42 (-1.50, 0.66) 0.444 [-0.16 (-0.63, 0.32)]
Week 4		35 3.1 (2.46)			33 2.9 (2.58)		
Week 4 chg		35 -3.6 (3.00)	-3.51 (0.38)		33 -3.7 (2.39)	-3.70 (0.39)	-0.19 (-1.28, 0.89) 0.729 [-0.07 (-0.55, 0.41)]
Week 6		34 3.7 (2.83)			33 2.2 (2.41)		
Week 6 chg		34 -2.9 (3.10)	-2.84 (0.38)		33 -4.4 (2.46)	-4.44 (0.39)	-1.60 (-2.69, -0.51) 0.004 [-0.57 (-1.06, -0.08)]
Week 8		35 2.8 (2.16)			33 1.9 (1.86)		
Week 8 chg		35 -3.9 (2.58)	-3.78 (0.38)		33 -4.8 (2.16)	-4.78 (0.39)	-1.00 (-2.09, 0.08) 0.070 [-0.42 (-0.90, 0.06)]
Week 10		35 2.6 (2.56)			33 2.2 (2.74)		
Week 10 chg		35 -4.1 (2.98)	-3.96 (0.38)		33 -4.4 (2.92)	-4.44 (0.39)	-0.47 (-1.56, 0.61) 0.390 [-0.16 (-0.64, 0.32)]
Week 12		34 2.5 (2.25)			33 2.1 (2.47)		
Week 12 chg		34 -4.1 (2.81)	-3.98 (0.38)		33 -4.6 (2.69)	-4.55 (0.39)	-0.57 (-1.66, 0.52) 0.303 [-0.21 (-0.69, 0.27)]
Week 14		33 2.2 (2.35)			33 2.0 (2.50)		

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0939
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

12MAY21 16:53 LP0162-Payer /p_mmrm3/t_t_csa_g45_46_w26.txt

Table 1.17.445.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	33	-4.6 (2.94)	-4.33 (0.39)	33	-4.7 (2.82)	-4.66 (0.39)	-0.33 (-1.42, 0.76) [-0.11 (-0.60, 0.37)]	0.550
Week 16	32	1.9 (2.08)		31	1.9 (2.43)			
Week 16 chg	32	-4.8 (2.70)	-4.58 (0.39)	31	-4.8 (2.80)	-4.81 (0.40)	-0.23 (-1.34, 0.87) [-0.08 (-0.58, 0.41)]	0.679
Week 18	30	2.0 (1.82)		31	1.6 (2.17)			
Week 18 chg	30	-4.7 (2.34)	-4.56 (0.40)	31	-5.1 (2.55)	-4.98 (0.40)	-0.42 (-1.53, 0.69) [-0.17 (-0.68, 0.33)]	0.454
Week 20	27	1.9 (2.26)		30	1.5 (2.27)			
Week 20 chg	27	-4.8 (2.93)	-4.65 (0.41)	30	-5.1 (2.40)	-5.10 (0.40)	-0.44 (-1.58, 0.69) [-0.17 (-0.69, 0.35)]	0.440
Week 22	27	1.4 (1.76)		28	1.1 (1.44)			
Week 22 chg	27	-5.0 (2.76)	-4.89 (0.41)	28	-5.4 (2.21)	-5.16 (0.41)	-0.28 (-1.42, 0.86) [-0.11 (-0.64, 0.42)]	0.634
Week 24	27	1.4 (1.80)		29	1.1 (1.86)			
Week 24 chg	27	-5.0 (2.71)	-4.91 (0.41)	29	-5.4 (2.38)	-5.36 (0.41)	-0.45 (-1.59, 0.68) [-0.18 (-0.70, 0.35)]	0.431
Week 26	31	1.4 (1.79)		31	1.5 (2.16)			
Week 26 chg	31	-5.2 (2.40)	-5.07 (0.39)	31	-5.2 (2.35)	-5.19 (0.40)	-0.12 (-1.22, 0.99) [-0.05 (-0.55, 0.45)]	0.836

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0939
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

12MAY21 16:53 LP0162-Payer /p_mmrm3/t_t_csa_g45_46_w26.txt

Table 1.17.445.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	101 6.8 (2.26)		105	105 6.7 (2.47)			
Week 2		101 4.4 (2.87)			105 3.9 (2.72)			
Week 2 chg		101 -2.4 (3.05)	-2.32 (0.27)		105 -2.8 (3.00)	-2.79 (0.26)	-0.47 (-1.20, 0.27) [-0.15 (-0.43, 0.12)]	0.211
Week 4		99 3.5 (2.84)			104 2.8 (2.73)			
Week 4 chg		99 -3.2 (3.40)	-3.11 (0.27)		104 -3.8 (3.16)	-3.81 (0.26)	-0.70 (-1.44, 0.03) [-0.21 (-0.49, 0.06)]	0.061
Week 6		98 3.4 (2.91)			101 2.7 (2.63)			
Week 6 chg		98 -3.3 (3.38)	-3.24 (0.27)		101 -4.0 (2.92)	-3.92 (0.26)	-0.69 (-1.42, 0.05) [-0.22 (-0.50, 0.06)]	0.068
Week 8		98 3.3 (2.85)			97 2.4 (2.64)			
Week 8 chg		98 -3.5 (3.52)	-3.38 (0.27)		97 -4.3 (3.12)	-4.17 (0.26)	-0.79 (-1.53, -0.05) [-0.24 (-0.52, 0.04)]	0.036
Week 10		96 3.2 (2.85)			97 2.2 (2.51)			
Week 10 chg		96 -3.7 (3.52)	-3.51 (0.27)		97 -4.5 (2.95)	-4.43 (0.26)	-0.92 (-1.67, -0.18) [-0.28 (-0.57, -0.00)]	0.015
Week 12		94 3.1 (2.81)			95 2.1 (2.50)			
Week 12 chg		94 -3.8 (3.56)	-3.61 (0.27)		95 -4.6 (3.07)	-4.53 (0.27)	-0.91 (-1.66, -0.17) [-0.28 (-0.56, 0.01)]	0.016
Week 14		93 3.0 (3.11)			94 2.4 (2.63)			

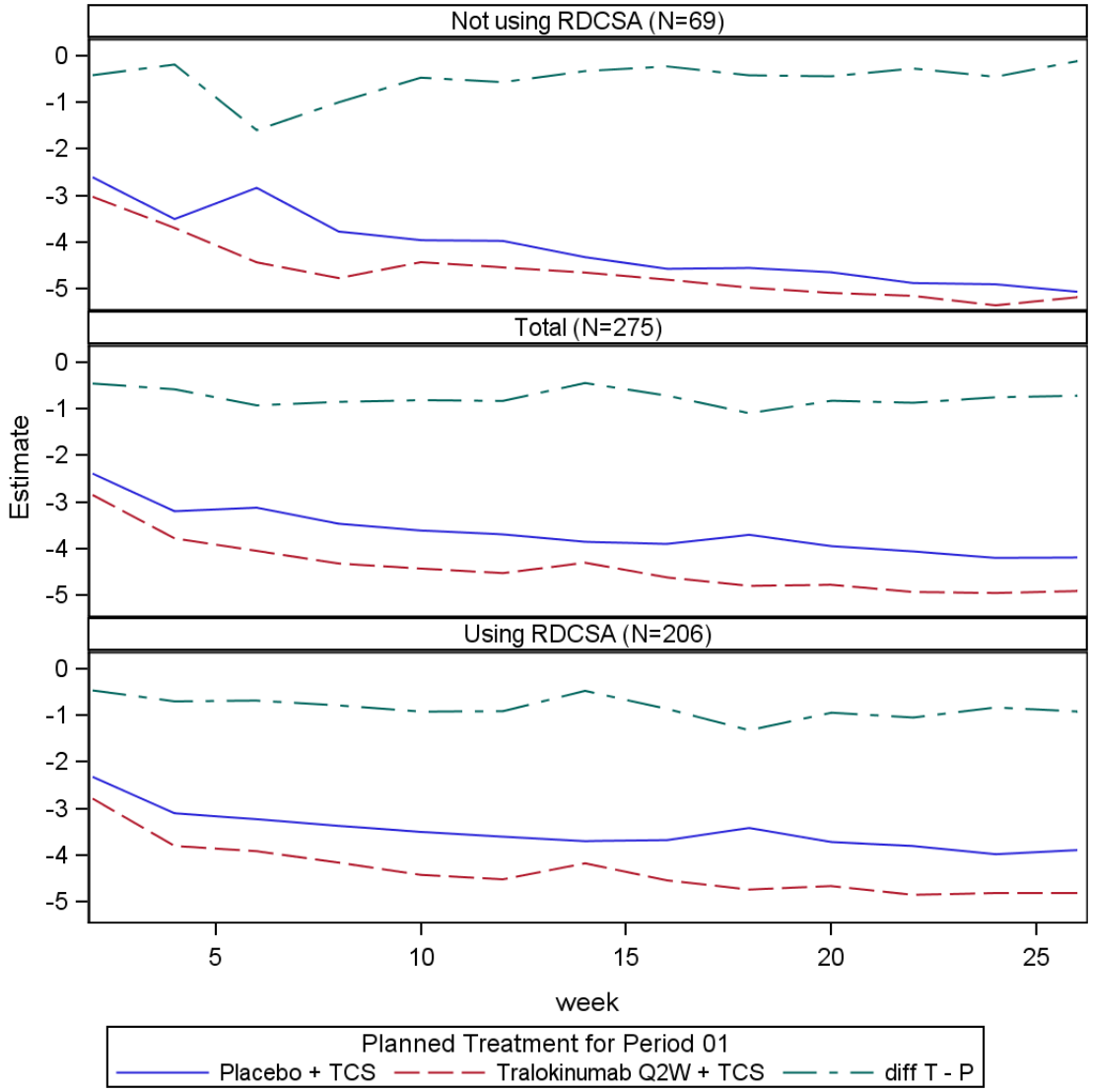
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0939
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change in VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.17.445.4.1: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Week 14 chg	93	-3.8 (3.65)	-3.71 (0.27)	94	-4.3 (3.16)	-4.18 (0.27)	-0.48 (-1.22, 0.27) [-0.14 (-0.43, 0.15)]	0.209
Week 16	92	3.0 (2.93)		92	2.0 (2.39)			
Week 16 chg	92	-3.8 (3.40)	-3.68 (0.27)	92	-4.6 (2.98)	-4.55 (0.27)	-0.87 (-1.61, -0.12) [-0.27 (-0.56, 0.02)]	0.023
Week 18	86	3.3 (3.05)		84	1.7 (2.32)			
Week 18 chg	86	-3.6 (3.60)	-3.42 (0.27)	84	-4.7 (3.07)	-4.75 (0.27)	-1.32 (-2.08, -0.57) [-0.40 (-0.70, -0.09)]	<.001
Week 20	80	2.8 (2.82)		87	1.9 (2.41)			
Week 20 chg	80	-3.9 (3.23)	-3.72 (0.28)	87	-4.7 (3.15)	-4.67 (0.27)	-0.95 (-1.71, -0.19) [-0.30 (-0.60, 0.01)]	0.015
Week 22	85	2.8 (2.88)		86	1.6 (2.15)			
Week 22 chg	85	-4.0 (3.49)	-3.81 (0.27)	86	-4.9 (3.03)	-4.86 (0.27)	-1.05 (-1.81, -0.29) [-0.32 (-0.62, -0.02)]	0.007
Week 24	85	2.5 (2.70)		88	1.6 (2.10)			
Week 24 chg	85	-4.2 (3.30)	-3.99 (0.27)	88	-4.9 (2.93)	-4.82 (0.27)	-0.83 (-1.59, -0.08) [-0.27 (-0.57, 0.03)]	0.030
Week 26	87	2.8 (2.88)		94	1.7 (2.05)			
Week 26 chg	87	-4.1 (3.29)	-3.90 (0.27)	94	-4.9 (2.95)	-4.82 (0.27)	-0.92 (-1.67, -0.17) [-0.30 (-0.59, -0.00)]	0.016

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.0939
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 VAS = Treatment*Week + [Baseline VAS]*Week + Prior CSA use + 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 Prior CSA use, 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 an unrestricted covariance model.

Figure 1.17.445.4.2: Total, RDSCA Use, change in SCORAD (Sleep loss VAS component), Treatment policy, LP0162-1346, Week 26



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 VAS = Treatment*Week + [Baseline VAS]*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 Prior CSA use, 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 an unrestricted covariance model.

Table 1.17.446.4.1: Total, RDSCA Use, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
EASI Score							
Total							
Baseline	137	137 33.8 (13.46)		138	138 32.1 (11.53)		
Week 16		124 10.5 (11.42)			123 6.4 (7.63)		
Week 16 chg		124 -23.8 (14.93)	-22.89 (0.84)		123 -25.9 (12.78)	-26.75 (0.84)	-3.86 (-6.21, -1.51) 0.001 [-0.28 (-0.53, -0.03)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5689
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.446.4.1: Total, RDSCA Use, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 31.9 (13.21)		33	33 30.2 (8.24)		
Week 16		32 7.2 (9.39)			31 4.2 (7.25)		
Week 16 chg		32 -25.0 (12.94)	-24.36 (1.44)		31 -26.2 (11.01)	-27.10 (1.47)	-2.74 (-6.86, 1.37) 0.187 [-0.23 (-0.72, 0.27)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5689
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.446.4.1: Total, RDSCA Use, change in EASI, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA							
Baseline	101	101 34.5 (13.55)		105	105 32.7 (12.35)		
Week 16		92 11.7 (11.87)			92 7.1 (7.65)		
Week 16 chg		92 -23.3 (15.61)	-22.41 (1.02)		92 -25.7 (13.37)	-26.64 (1.02)	-4.23 (-7.09, -1.38) 0.004 [-0.29 (-0.58, -0.00)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.5689
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 2, change is imputed as 0. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.463.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary							
Total							
Baseline	137	134 44.5 (8.19)		138	134 44.5 (7.83)		
Week 8		129 50.3 (7.06)			129 51.7 (7.07)		
Week 8 chg		129 5.6 (7.75)	5.69 (0.56)		129 7.4 (7.27)	7.16 (0.56)	1.47 (-0.08, 3.03) 0.063 [0.20 (-0.05, 0.44)]
Week 16		119 50.9 (7.78)			113 52.9 (6.85)		
Week 16 chg		119 6.8 (8.15)	6.49 (0.57)		113 8.0 (7.67)	7.87 (0.58)	1.39 (-0.22, 2.99) 0.090 [0.17 (-0.08, 0.43)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3884
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.463.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA								
Baseline	36	36 44.6 (6.77)		33	31 44.9 (7.06)			
Week 8		36 49.7 (6.97)			30 52.5 (6.61)			
Week 8 chg		36 5.1 (6.87)	5.20 (0.92)		30 7.7 (6.14)	7.79 (1.00)	2.59 (-0.10, 5.29) [0.40 (-0.09, 0.89)]	0.059
Week 16		30 51.5 (6.36)			27 51.6 (6.60)			
Week 16 chg		30 7.4 (6.47)	7.04 (0.99)		27 7.2 (5.75)	7.37 (1.04)	0.33 (-2.52, 3.17) [0.05 (-0.47, 0.57)]	0.821

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3884
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.463.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA												
Baseline	101	98	44.4 (8.69)			105	103	44.4 (8.08)				
Week 8		93	50.5 (7.12)				99	51.5 (7.22)				
Week 8 chg		93	5.7 (8.10)	5.89	(0.68)		99	7.2 (7.60)	6.94	(0.66)	1.04 (-0.82, 2.91) [0.13 (-0.15, 0.42)]	0.271
Week 16		89	50.7 (8.23)				86	53.2 (6.91)				
Week 16 chg		89	6.6 (8.67)	6.35	(0.69)		86	8.2 (8.20)	7.99	(0.68)	1.63 (-0.27, 3.54) [0.19 (-0.10, 0.49)]	0.093

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3884
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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.

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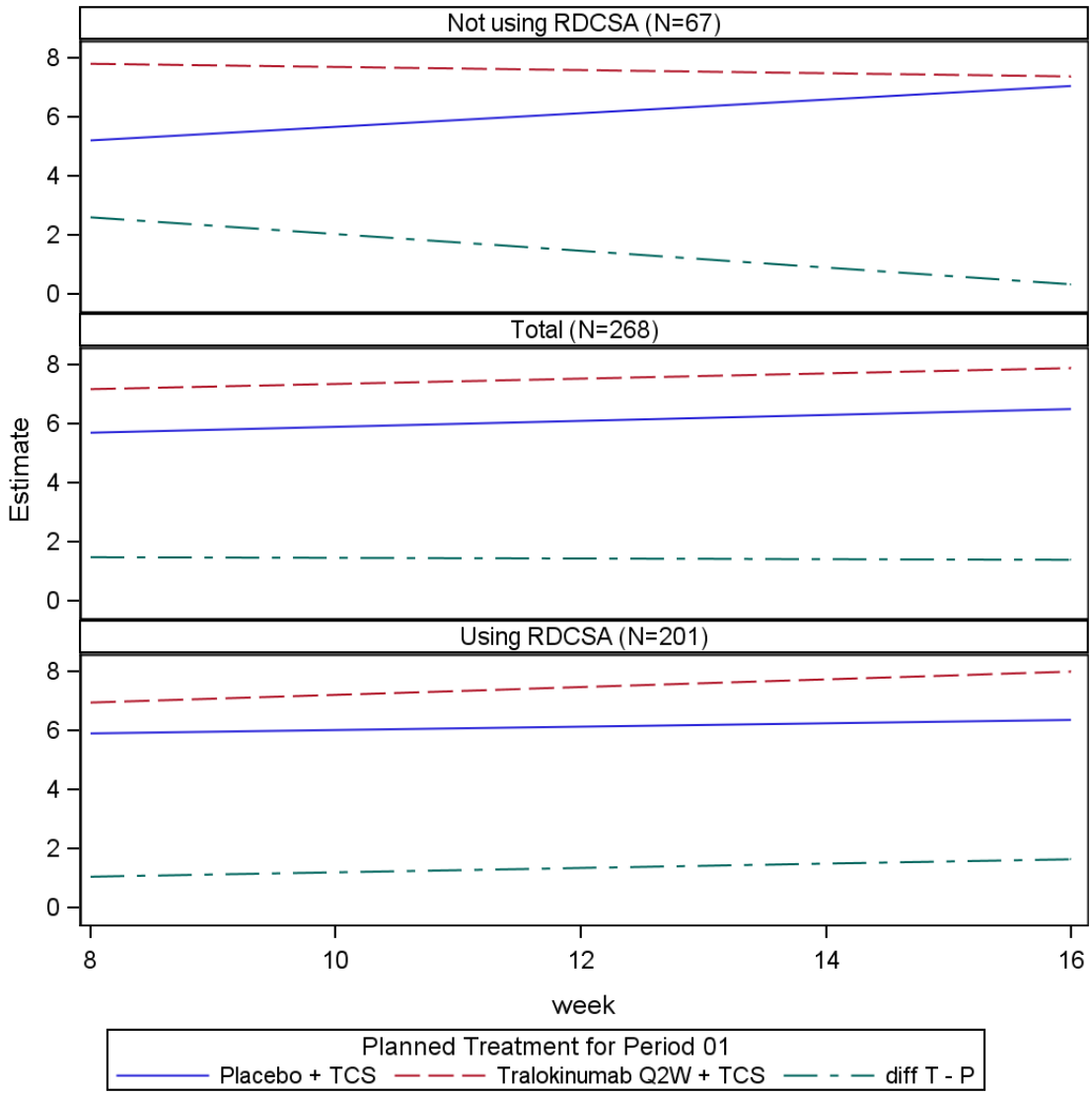
Figure 1.17.463.4.2: Total, RDSCA Use, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 16



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.464.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary							
Total							
Baseline	137	134 44.9 (11.42)		138	134 46.3 (9.74)		
Week 8		129 49.6 (10.25)			129 49.7 (9.51)		
Week 8 chg		129 4.4 (7.37)	4.13 (0.64)		129 3.7 (8.69)	3.69 (0.63)	-0.44 (-2.21, 1.33) 0.625 [-0.05 (-0.30, 0.19)]
Week 16		119 49.5 (10.11)			113 49.9 (9.68)		
Week 16 chg		119 4.4 (8.65)	4.08 (0.65)		113 3.4 (8.59)	3.59 (0.66)	-0.50 (-2.32, 1.33) 0.594 [-0.06 (-0.32, 0.20)]
Week 26		110 50.4 (9.75)			112 51.4 (7.72)		
Week 26 chg		110 5.5 (8.68)	4.92 (0.67)		112 4.6 (8.26)	4.50 (0.66)	-0.42 (-2.27, 1.44) 0.660 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4306
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.464.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Not using RDCSA										
Baseline	36	36	46.4 (11.03)		33	31	47.6 (9.14)			
Week 8		36	50.5 (10.08)			30	50.7 (7.31)			
Week 8 chg		36	4.1 (8.68)	3.90 (1.15)		30	3.5 (7.28)	3.63 (1.25)	-0.27 (-3.64, 3.10) [-0.03 (-0.52, 0.45)]	0.874
Week 16		30	51.5 (10.31)			27	49.0 (8.63)			
Week 16 chg		30	4.3 (9.95)	4.16 (1.21)		27	1.9 (7.34)	1.97 (1.29)	-2.20 (-5.71, 1.32) [-0.25 (-0.77, 0.27)]	0.218
Week 26		31	52.8 (8.04)			26	50.7 (7.51)			
Week 26 chg		31	6.5 (9.21)	5.94 (1.20)		26	3.5 (7.68)	3.31 (1.30)	-2.63 (-6.15, 0.89) [-0.31 (-0.83, 0.22)]	0.141

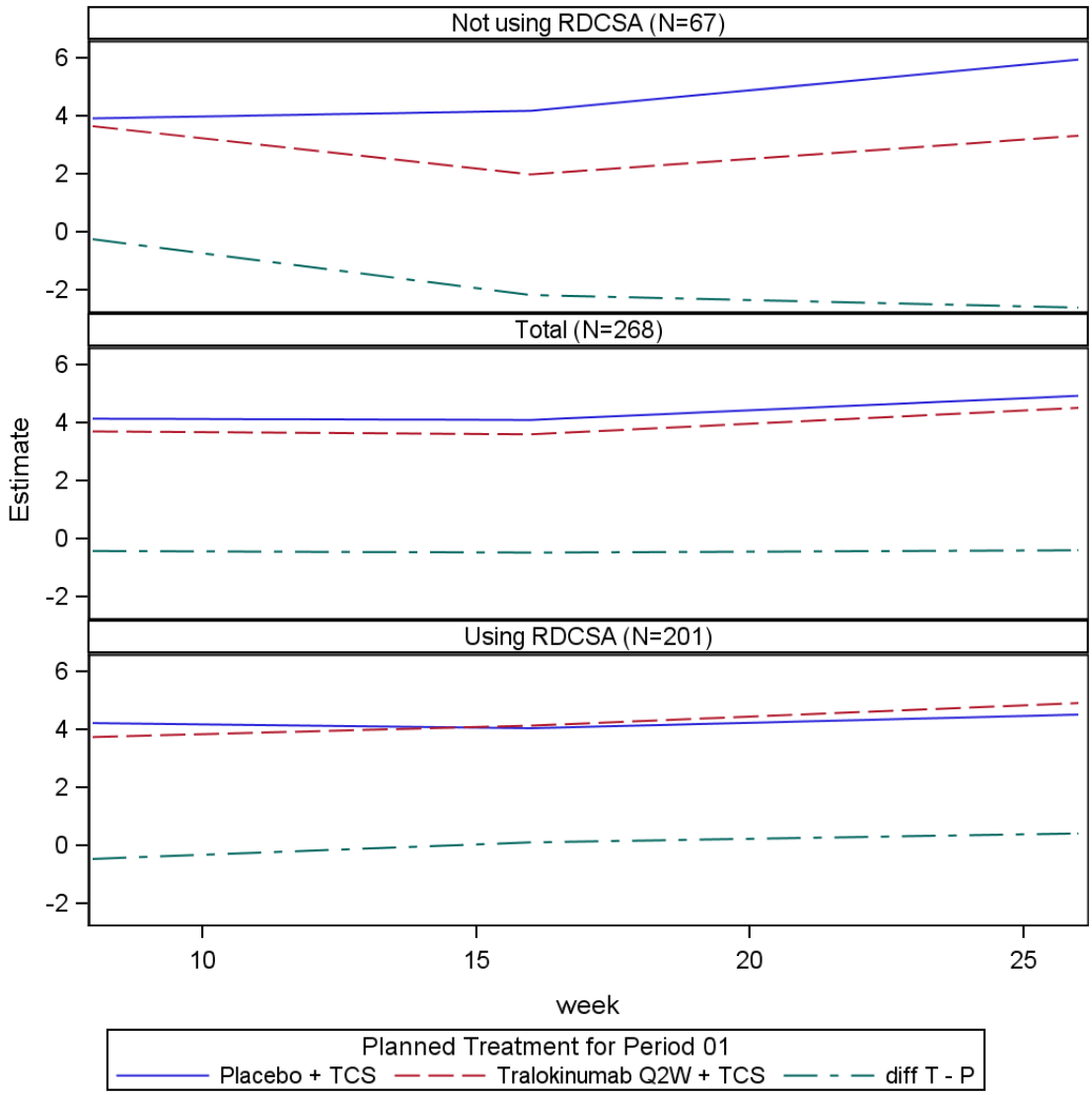
SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4306
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Repeated measurements model on post-baseline data: Change = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.464.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA									
Baseline	101	98	44.3 (11.57)		105	103	45.9 (9.93)		
Week 8		93	49.2 (10.34)			99	49.4 (10.10)		
Week 8 chg		93	4.5 (6.84)	4.21 (0.76)		99	3.7 (9.10)	3.73 (0.73)	-0.48 (-2.56, 1.59) 0.649 [-0.06 (-0.34, 0.22)]
Week 16		89	48.8 (10.01)			86	50.2 (10.02)		
Week 16 chg		89	4.4 (8.22)	4.03 (0.77)		86	3.9 (8.94)	4.12 (0.77)	0.09 (-2.05, 2.23) 0.934 [0.01 (-0.29, 0.31)]
Week 26		79	49.5 (10.24)			86	51.6 (7.81)		
Week 26 chg		79	5.1 (8.48)	4.50 (0.80)		86	4.9 (8.45)	4.90 (0.77)	0.40 (-1.79, 2.58) 0.720 [0.05 (-0.26, 0.35)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4306
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.464.4.2: Total, RDSCA Use, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.465.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Physical component summary												
Total												
Baseline	137	134	44.5 (8.19)			138	134	44.5 (7.83)				
Week 8		129	50.3 (7.06)				129	51.7 (7.07)				
Week 8 chg		129	5.6 (7.75)	5.70	(0.56)		129	7.4 (7.27)	7.18	(0.56)	1.48 (-0.09, 3.04) [0.20 (-0.05, 0.44)]	0.064
Week 16		119	50.9 (7.78)				113	52.9 (6.85)				
Week 16 chg		119	6.8 (8.15)	6.57	(0.57)		113	8.0 (7.67)	7.95	(0.58)	1.37 (-0.23, 2.98) [0.17 (-0.08, 0.43)]	0.093
Week 26		110	50.7 (7.62)				112	52.9 (7.40)				
Week 26 chg		110	6.9 (8.19)	6.11	(0.59)		112	8.2 (7.71)	8.22	(0.58)	2.11 (0.48, 3.74) [0.27 (0.00, 0.53)]	0.011

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1240
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.465.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 44.6 (6.77)		33	31 44.9 (7.06)		
Week 8		36 49.7 (6.97)			30 52.5 (6.61)		
Week 8 chg		36 5.1 (6.87)	5.25 (0.93)		30 7.7 (6.14)	7.83 (1.01)	2.58 (-0.14, 5.30) 0.063 [0.39 (-0.10, 0.88)]
Week 16		30 51.5 (6.36)			27 51.6 (6.60)		
Week 16 chg		30 7.4 (6.47)	7.26 (1.00)		27 7.2 (5.75)	7.36 (1.06)	0.10 (-2.79, 2.98) 0.947 [0.02 (-0.50, 0.54)]
Week 26		31 50.2 (7.24)			26 53.4 (5.34)		
Week 26 chg		31 6.1 (7.27)	5.46 (0.99)		26 9.2 (6.42)	9.41 (1.08)	3.95 (1.06, 6.84) 0.008 [0.57 (0.04, 1.10)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1240
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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.

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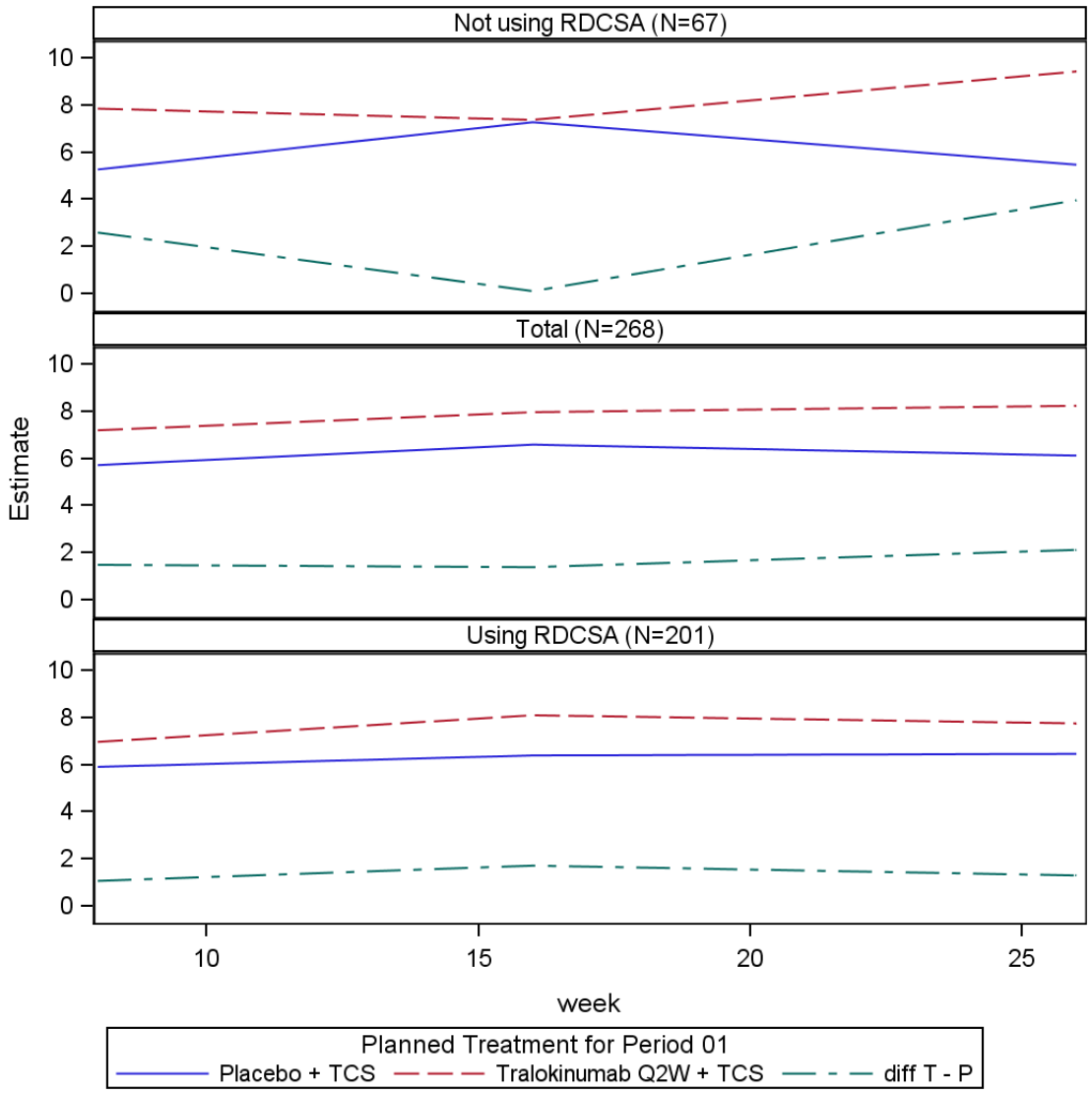
Table 1.17.465.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA											
Baseline	101	98	44.4 (8.69)			105	103	44.4 (8.08)			
Week 8		93	50.5 (7.12)				99	51.5 (7.22)			
Week 8 chg		93	5.7 (8.10)	5.89	(0.68)		99	7.2 (7.60)	6.95	(0.66)	1.06 (-0.81, 2.93) 0.267 [0.13 (-0.15, 0.42)]
Week 16		89	50.7 (8.23)				86	53.2 (6.91)			
Week 16 chg		89	6.6 (8.67)	6.38	(0.69)		86	8.2 (8.20)	8.08	(0.68)	1.71 (-0.21, 3.62) 0.080 [0.20 (-0.10, 0.50)]
Week 26		79	51.0 (7.80)				86	52.7 (7.94)			
Week 26 chg		79	7.2 (8.54)	6.45	(0.71)		86	7.9 (8.07)	7.74	(0.68)	1.29 (-0.65, 3.23) 0.191 [0.16 (-0.15, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1240
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.465.4.2: Total, RDSCA Use, change in SF-36 Physical Component Summary, Treatment policy, LP0162-1346, Week 26



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.466.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 8		129	49.6 (10.25)				129	49.7 (9.51)			
Week 8 chg		129	4.4 (7.37)	4.14	(0.65)		129	3.7 (8.69)	3.66	(0.65)	-0.47 (-2.28, 1.34) 0.607 [-0.06 (-0.30, 0.19)]
Week 16		119	49.5 (10.11)				113	49.9 (9.68)			
Week 16 chg		119	4.4 (8.65)	4.09	(0.67)		113	3.4 (8.59)	3.63	(0.68)	-0.46 (-2.34, 1.42) 0.629 [-0.05 (-0.31, 0.20)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4695
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.466.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 46.4 (11.03)		33	31 47.6 (9.14)		
Week 8		36 50.5 (10.08)			30 50.7 (7.31)		
Week 8 chg		36 4.1 (8.68)	3.87 (1.19)		30 3.5 (7.28)	3.67 (1.30)	-0.20 (-3.71, 3.31) 0.910 [-0.02 (-0.51, 0.46)]
Week 16		30 51.5 (10.31)			27 49.0 (8.63)		
Week 16 chg		30 4.3 (9.95)	4.11 (1.28)		27 1.9 (7.34)	1.91 (1.35)	-2.20 (-5.90, 1.49) 0.239 [-0.25 (-0.77, 0.27)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4695
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.466.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA												
Baseline	101	98	44.3 (11.57)			105	103	45.9 (9.93)				
Week 8		93	49.2 (10.34)				99	49.4 (10.10)				
Week 8 chg		93	4.5 (6.84)	4.21	(0.77)		99	3.7 (9.10)	3.69	(0.75)	-0.53 (-2.65, 1.59) [-0.07 (-0.35, 0.22)]	0.625
Week 16		89	48.8 (10.01)				86	50.2 (10.02)				
Week 16 chg		89	4.4 (8.22)	4.06	(0.78)		86	3.9 (8.94)	4.19	(0.79)	0.13 (-2.06, 2.32) [0.02 (-0.28, 0.31)]	0.907

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.4695
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa 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 = Treatment*Week + [Baseline]*Week + Prior CSA use + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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.

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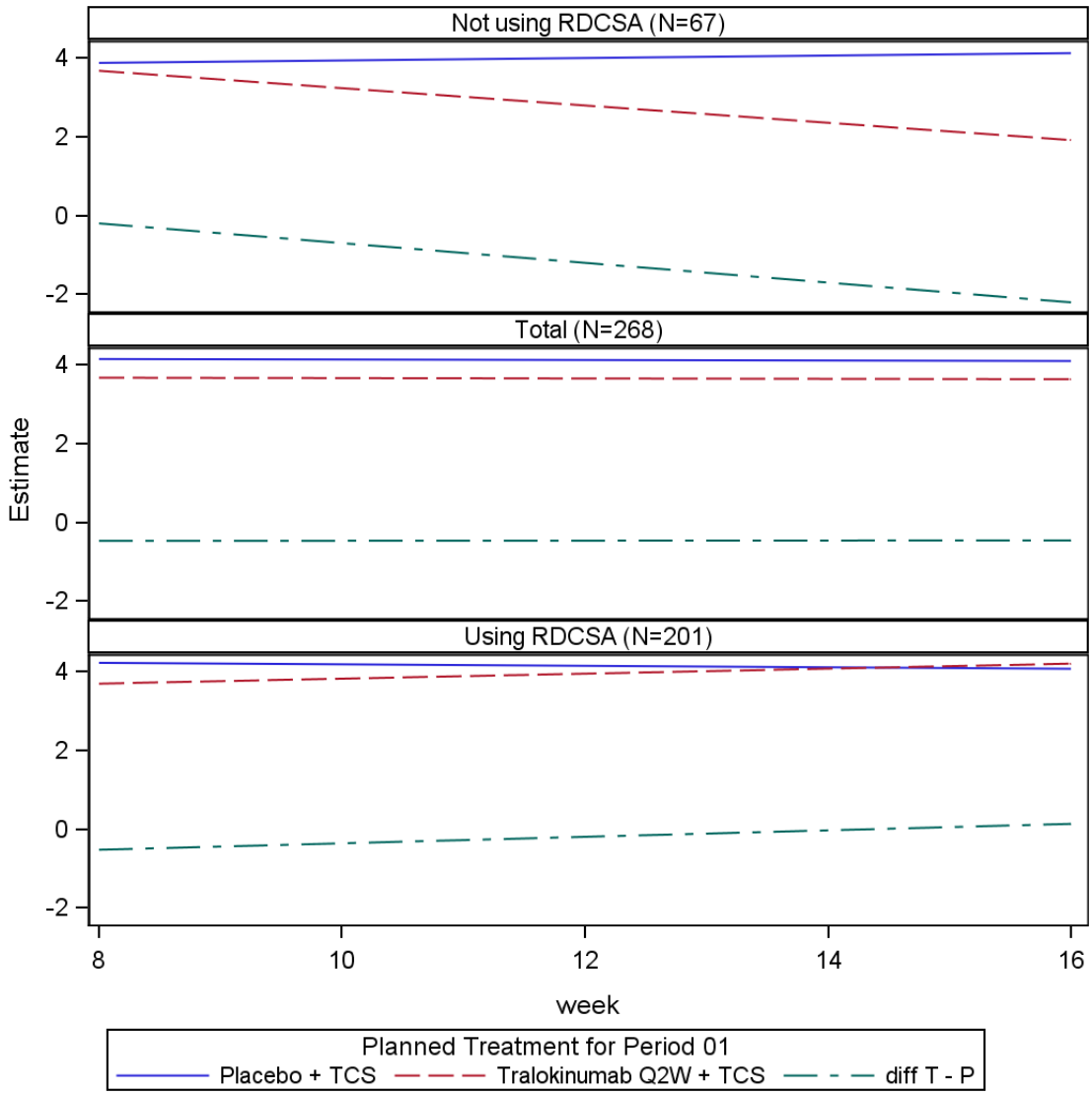
Figure 1.17.466.4.2: Total, RDSCA Use, change in SF-36 Mental Component Summary, Treatment policy, LP0162-1346, Week 16



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 = Treatment*Week + [Baseline]*Week + Region + Baseline IGA. In case of no post-baseline assessments before initiation of rescue medication, the Week 8, 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 Prior CSA use, 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 1.17.469.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 26		115	50.7 (9.70)				118	51.1 (7.88)			
Week 26 chg		113	5.6 (8.87)	5.14	(0.66)		114	4.4 (8.31)	4.80	(0.66)	-0.34 (-2.18, 1.50) 0.715 [-0.04 (-0.30, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1578
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.469.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 46.4 (11.03)		33	31 47.6 (9.14)		
Week 26		32 53.1 (8.09)			28 50.0 (8.32)		
Week 26 chg		32 6.3 (9.15)	6.21 (1.12)		26 3.5 (7.68)	3.66 (1.24)	-2.54 (-5.89, 0.80) 0.133 [-0.30 (-0.82, 0.22)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1578
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.469.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA											
Baseline	101	98	44.3 (11.57)			105	103	45.9 (9.93)			
Week 26		83	49.7 (10.15)				90	51.5 (7.75)			
Week 26 chg		81	5.4 (8.80)	4.77	(0.80)		88	4.7 (8.51)	5.15	(0.77)	0.39 (-1.81, 2.58) 0.727 [0.04 (-0.26, 0.35)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.1578
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.470.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary											
Total											
Baseline	137	134	44.5 (8.19)			138	134	44.5 (7.83)			
Week 26		115	50.9 (7.60)				118	52.8 (7.38)			
Week 26 chg		113	6.8 (8.15)	6.63	(0.62)		114	8.4 (7.77)	8.47	(0.62)	1.84 (0.11, 3.56) 0.037 [0.23 (-0.03, 0.49)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3100
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.470.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 44.6 (6.77)		33	31 44.9 (7.06)		
Week 26		32 50.0 (7.20)			28 52.9 (5.63)		
Week 26 chg		32 5.9 (7.22)	5.88 (1.01)		26 9.2 (6.42)	9.23 (1.12)	3.34 (0.32, 6.37) 0.031 [0.49 (-0.04, 1.01)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3100
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.470.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 26

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA											
Baseline	101	98	44.4 (8.69)			105	103	44.4 (8.08)			
Week 26		83	51.3 (7.76)				90	52.8 (7.87)			
Week 26 chg		81	7.1 (8.51)	6.91	(0.76)		88	8.1 (8.14)	8.23	(0.73)	1.31 (-0.77, 3.40) 0.215 [0.16 (-0.14, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.3100
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.471.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Mental component summary											
Total											
Baseline	137	134	44.9 (11.42)			138	134	46.3 (9.74)			
Week 16		121	49.5 (10.08)				117	50.1 (9.57)			
Week 16 chg		119	4.4 (8.65)	4.12	(0.70)		113	3.4 (8.59)	3.70	(0.72)	-0.42 (-2.41, 1.56) 0.675 [-0.05 (-0.31, 0.21)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2644
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.471.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 46.4 (11.03)		33	31 47.6 (9.14)		
Week 16		30 51.5 (10.31)			29 49.2 (8.40)		
Week 16 chg		30 4.3 (9.95)	4.18 (1.40)		27 1.9 (7.34)	1.85 (1.47)	-2.33 (-6.40, 1.73) 0.255 [-0.26 (-0.79, 0.26)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2644
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.471.4.1: Total, RDSCA Use, change in SF-36 Mental Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Using RDCSA											
Baseline	101	98	44.3 (11.57)			105	103	45.9 (9.93)			
Week 16		91	48.8 (9.97)				88	50.4 (9.95)			
Week 16 chg		89	4.4 (8.22)	4.07	(0.81)		86	3.9 (8.94)	4.29	(0.82)	0.23 (-2.06, 2.51) 0.845 [0.03 (-0.27, 0.32)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2644
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.472.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n	Placebo + TCS Raw mean (sd)	Placebo + TCS Least Squares mean	Placebo + TCS Least Squares (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n	Tralokinumab Q2W + TCS Raw mean (sd)	Tralokinumab Q2W + TCS Least Squares mean	Tralokinumab Q2W + TCS Least Squares (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Physical component summary											
Total											
Baseline	137	134	44.5 (8.19)			138	134	44.5 (7.83)			
Week 16		121	51.0 (7.75)				117	52.8 (6.79)			
Week 16 chg		119	6.8 (8.15)	6.60	(0.60)		113	8.0 (7.67)	8.20	(0.61)	1.60 (-0.09, 3.28) 0.063 [0.20 (-0.06, 0.46)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2928
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.472.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) p-value [SMD]
Not using RDCSA							
Baseline	36	36 44.6 (6.77)		33	31 44.9 (7.06)		
Week 16		30 51.5 (6.36)			29 51.3 (6.53)		
Week 16 chg		30 7.4 (6.47)	7.40 (0.93)		27 7.2 (5.75)	7.34 (0.98)	-0.07 (-2.76, 2.63) 0.961 [-0.01 (-0.53, 0.51)]

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2928
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.472.4.1: Total, RDSCA Use, change in SF-36 Physical Component Summary, ANCOVA sensitivity, LP0162-1346, Week 16

Subgroup/visit	Placebo + TCS N	Placebo + TCS Raw n mean (sd)	Placebo + TCS Least Squares mean (se)	Tralokinumab Q2W + TCS N	Tralokinumab Q2W + TCS Raw n mean (sd)	Tralokinumab Q2W + TCS Least Squares mean (se)	Tralokinumab-Placebo Least Squares (95% CI) [SMD]	p-value
Using RDCSA								
Baseline	101	98 44.4 (8.69)		105	103 44.4 (8.08)			
Week 16		91 50.8 (8.18)			88 53.3 (6.84)			
Week 16 chg		89 6.6 (8.67)	6.36 (0.72)		86 8.2 (8.20)	8.47 (0.74)	2.11 (0.07, 4.14) [0.25 (-0.05, 0.55)]	0.043

SMD: Hedges' g (Least squares estimate normalized with common variance estimate of raw differences)
Test for treatment and subgroup interaction: 0.2928
Interaction test: test for trt01p*week*subgroup in repeated model trt01p*week base*week studyid rdcsa baseiga trt01p*week*subgroup .
Data collected after permanent discontinuation of investigational medicinal product [IMP] or initiation of rescue medication is included. Model of Change in EASI = Treatment + Baseline + RDSCA + Baseline IGA. Treatment effect is estimated as the least squares treatment difference using observed margins. Change from baseline is analysed in a linear effects model including treatment, Prior CSA use and IGA strata as fixed effects and baseline value as covariate.

Table 1.17.701.4.1: Total, Any TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	0.2985	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385
Not using RDCSA		0.3026	0.86 (0.64, 1.15)	0.57 (0.19, 1.66)	-11 (-32, 9.75)	28	(77.8)	116	22	(66.7)	58
Using RDCSA		0.7400	1.02 (0.89, 1.17)	1.12 (0.57, 2.22)	1.9 (-9.1, 12.8)	80	(79.2)	307	85	(81.0)	327

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 1.17.702.4.1: Total, Any drug-related TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	0.0528	0.2852	1.19 (0.86, 1.65)	1.32 (0.80, 2.17)	6.1 (-5.0, 17.3)	43	(31.4)	94	52	(37.7)	105
Not using RDCSA		0.2002	0.54 (0.21, 1.41)	0.45 (0.13, 1.53)	-13 (-32, 6.10)	10	(27.8)	19	5	(15.2)	7
Using RDCSA		0.0791	1.36 (0.96, 1.94)	1.66 (0.94, 2.94)	12.0 (-1.2, 25.1)	33	(32.7)	75	47	(44.8)	98

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 1.17.703.4.1: Total, Any TEAE causing permanent discontinuation, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	Not est.	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3	(2.2)	4	1	(0.7)	1
Using RDCSA		0.3045	0.32 (0.03, 3.22)	0.32 (0.03, 3.11)	-2.0 (-5.8, 1.81)	3	(3.0)	4	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. TEAE: Treatment emergent adverse events

Table 1.17.704.4.1: Total, Any mild TEAE, LP0162-1346, 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 + TCS n (%)	E	Tralokinumab Q2W + TCS n (%)	E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Not using RDCSA						36 17.1		33 16.3	
Using RDCSA						101 48.3		105 49.1	
Any system organ class									
Any preferred term									
Total	0.3616	0.9615	1.00 (0.87, 1.16)	1.01 (0.60, 1.71)	0.3 (-10, 10.9)	98 (71.5)	293	99 (71.7)	300
Not using RDCSA		0.4450	0.87 (0.61, 1.24)	0.68 (0.25, 1.83)	-8.9 (-31, 13.6)	25 (69.4)	74	20 (60.6)	51
Using RDCSA		0.6162	1.04 (0.89, 1.23)	1.17 (0.63, 2.18)	3.1 (-8.9, 15.1)	73 (72.3)	219	79 (75.2)	249

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 1.17.705.4.1: Total, Any moderate TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	0.0170	0.0876	0.75 (0.53, 1.05)	0.65 (0.39, 1.07)	-9.8 (-21, 1.39)	53	(38.7)	121	40	(29.0)	82
Not using RDCSA		0.0039	0.32 (0.13, 0.76)	0.19 (0.06, 0.61)	-32 (-52, -12)	17	(47.2)	40	5	(15.2)	6
Using RDCSA		0.7307	0.94 (0.64, 1.36)	0.90 (0.51, 1.60)	-2.3 (-15, 10.7)	36	(35.6)	81	35	(33.3)	76

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 1.17.706.4.1: Total, Any severe TEAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	0.7192	0.1235	0.37 (0.10, 1.38)	0.36 (0.09, 1.39)	-3.7 (-8.3, 0.97)	8	(5.8)	9	3	(2.2)	3
Not using RDCSA		0.6149	0.55 (0.05, 5.74)	0.54 (0.05, 6.17)	-2.5 (-12, 7.03)	2	(5.6)	2	1	(3.0)	1
Using RDCSA		0.1362	0.32 (0.07, 1.55)	0.31 (0.06, 1.56)	-4.0 (-9.3, 1.27)	6	(5.9)	7	2	(1.9)	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. TEAE: Treatment emergent adverse events

Table 1.17.707.4.1: Total, Death, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Not using RDCSA					36	17.1		33	16.3	
Using RDCSA					101	48.3		105	49.1	

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.

Table 1.17.708.4.1: Total, Any TE SAE, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	0.3574	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5	(3.6)	9	1	(0.7)	1
Not using RDCSA		0.1753	0.00 (not est.)	0.00 (not est.)	-5.6 (-13, 1.92)	2	(5.6)	3	0	(0.0)	0
Using RDCSA		0.3045	0.33 (0.04, 3.05)	0.32 (0.03, 3.14)	-2.0 (-5.8, 1.81)	3	(3.0)	6	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. TE SAE: Treatment emergent serious adverse events

Table 1.17.709.4.1: Total, Any drug-related TE SAE, LP0162-1346, 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 + TCS n (%)	E	Tralokinumab Q2W + TCS n (%)	E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Not using RDCSA						36 17.1		33 16.3	
Using RDCSA						101 48.3		105 49.1	
Any system organ class									
Any preferred term									
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)	3	0 (0.0)	0
Using RDCSA		0.1552	0.00 (not est.)	0.00 (not est.)	-1.9 (-4.6, 0.75)	2 (2.0)	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 1.17.710.4.1: Total, Any TE SAE causing permanent discontinuation, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Not using RDCSA						36 17.1		33 16.3	
Using RDCSA						101 48.3		105 49.1	
Any system organ class									
Any preferred term									
Total	Not est.	0.1618	0.00 (not est.)	0.00 (not est.)	-1.4 (-3.4, 0.56)	2 (1.5)	3	0 (0.0)	0
Using RDCSA		0.1552	0.00 (not est.)	0.00 (not est.)	-1.9 (-4.6, 0.75)	2 (2.0)	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 1.17.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	0.2985	0.7999	0.98 (0.87, 1.11)	0.93 (0.52, 1.65)	-1.3 (-11, 8.50)	108	(78.8)	423	107	(77.5)	385
Not using RDCSA		0.3026	0.86 (0.64, 1.15)	0.57 (0.19, 1.66)	-11 (-32, 9.75)	28	(77.8)	116	22	(66.7)	58
Using RDCSA		0.7400	1.02 (0.89, 1.17)	1.12 (0.57, 2.22)	1.9 (-9.1, 12.8)	80	(79.2)	307	85	(81.0)	327
Eye disorders											
Any											
Total	0.9422	0.2842	1.54 (0.69, 3.44)	1.61 (0.67, 3.84)	3.6 (-3.0, 10.1)	9	(6.6)	14	14	(10.1)	17
Gastrointestinal disorders											
Any											
Total	0.8099	0.8349	0.93 (0.48, 1.81)	0.92 (0.44, 1.95)	-0.8 (-8.3, 6.68)	16	(11.7)	23	15	(10.9)	18
General disorders and administration site conditions											
Any											
Total	0.7541	0.1576	1.59 (0.83, 3.03)	1.70 (0.81, 3.57)	5.6 (-2.1, 13.3)	13	(9.5)	16	21	(15.2)	27
Infections and infestations											
Any											
Total	0.5887	0.2533	0.89 (0.72, 1.09)	0.76 (0.47, 1.22)	-6.8 (-18, 4.82)	83	(60.6)	152	74	(53.6)	144

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 1.17.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Upper respiratory tract infection											
Total	0.0928	0.9930	1.00 (0.43, 2.31)	1.00 (0.40, 2.47)	-0.0 (-6.2, 6.12)	10	(7.3)	11	10	(7.2)	12
Viral upper respiratory tract infection											
Total	0.9246	0.7928	1.05 (0.71, 1.57)	1.08 (0.63, 1.84)	1.4 (-9.0, 11.8)	35	(25.5)	46	37	(26.8)	53
Injury, poisoning and procedural complications											
Any											
Total	0.7579	0.5243	1.29 (0.59, 2.84)	1.32 (0.56, 3.08)	2.1 (-4.5, 8.74)	10	(7.3)	12	13	(9.4)	16
Musculoskeletal and connective tissue disorders											
Any											
Total	0.2759	0.4116	1.27 (0.72, 2.24)	1.32 (0.68, 2.57)	3.5 (-4.9, 12.0)	18	(13.1)	28	23	(16.7)	25
Nervous system disorders											
Any											
Total	0.7017	0.6516	1.13 (0.66, 1.94)	1.16 (0.61, 2.20)	2.0 (-6.7, 10.8)	21	(15.3)	31	24	(17.4)	33
Headache											
Total	0.9969	0.1506	1.61 (0.84, 3.09)	1.71 (0.82, 3.57)	5.7 (-2.0, 13.5)	13	(9.5)	18	21	(15.2)	25
Respiratory, thoracic and mediastinal disorders											
Any											
Total	0.0057	0.0335	0.55 (0.31, 0.96)	0.49 (0.25, 0.95)	-9.5 (-18, -.84)	29	(21.2)	38	16	(11.6)	21
Not using RDCSA		0.0043	0.00 (not est.)	0.00 (not est.)	-22 (-36, -8.6)	8	(22.2)	13	0	(0.0)	0
Using RDCSA		0.3047	0.73 (0.41, 1.32)	0.69 (0.34, 1.41)	-5.5 (-16, 4.98)	21	(20.8)	25	16	(15.2)	21
Skin and subcutaneous tissue disorders											
Any											

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

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Table 1.17.711.4.1: Total, Any TEAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Total	0.6494	0.1365	0.71 (0.46, 1.12)	0.65 (0.37, 1.15)	-7.5 (-17, 2.33)	36 (26.3)	59	26 (18.8)	44
Dermatitis atopic									
Total	0.6286	0.0498	0.44 (0.19, 1.03)	0.41 (0.16, 1.02)	-6.6 (-13, -.07)	16 (11.7)	26	7 (5.1)	11
Not using RDCSA		0.1885	0.27 (0.03, 2.21)	0.23 (0.02, 2.31)	-8.2 (-20, 3.42)	4 (11.1)	7	1 (3.0)	1
Using RDCSA		0.1239	0.49 (0.19, 1.24)	0.45 (0.16, 1.26)	-6.0 (-14, 1.62)	12 (11.9)	19	6 (5.7)	10
Vascular disorders									
Any									
Total	0.0258	0.0596	0.36 (0.12, 1.10)	0.34 (0.10, 1.09)	-5.2 (-11, 0.16)	11 (8.0)	12	4 (2.9)	6

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 1.17.712.4.1: Total, Any TESAE by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	0.3574	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5	(3.6)	9	1	(0.7)	1
Not using RDCSA		0.1753	0.00 (not est.)	0.00 (not est.)	-5.6 (-13, 1.92)	2	(5.6)	3	0	(0.0)	0
Using RDCSA		0.3045	0.33 (0.04, 3.05)	0.32 (0.03, 3.14)	-2.0 (-5.8, 1.81)	3	(3.0)	6	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. TE SAE: Treatment emergent serious adverse events

Table 1.17.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Not using RDCSA						36 17.1		33 16.3	
Using RDCSA						101 48.3		105 49.1	
Any system organ class									
Any preferred term									
Total	Not est.	0.3198	0.33 (0.03, 3.32)	0.33 (0.03, 3.22)	-1.4 (-4.3, 1.38)	3 (2.2)	4	1 (0.7)	1
Using RDCSA		0.3045	0.32 (0.03, 3.22)	0.32 (0.03, 3.11)	-2.0 (-5.8, 1.81)	3 (3.0)	4	1 (1.0)	1
General disorders and administration site conditions									
Any									
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0 (0.0)	0	1 (0.7)	1
Injection site pain									
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0 (0.0)	0	1 (0.7)	1
Nervous system disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Cerebrovascular accident									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Psychiatric disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	2	0 (0.0)	0
Depressed mood									

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

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Table 1.17.713.4.1: Total, Any TEAE causing permanent discontinuation by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Suicidal ideation									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis atopic									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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. TE SAE: Treatment emergent serious adverse events

Table 1.17.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	0.5329	0.0780	2.14 (0.90, 5.07)	2.28 (0.90, 5.77)	5.8 (-.58, 12.2)	7	(5.1)	9	15	(10.9)	17
Not using RDCSA		0.6117	1.45 (0.35, 5.95)	1.51 (0.31, 7.35)	3.7 (-11, 18.1)	3	(8.3)	4	4	(12.1)	5
Using RDCSA		0.0700	2.68 (0.88, 8.15)	2.89 (0.88, 9.46)	6.6 (-.38, 13.5)	4	(4.0)	5	11	(10.5)	12
Eye disorders											
Any											
Total	0.3689	0.1593	2.23 (0.71, 7.03)	2.30 (0.70, 7.57)	3.6 (-1.4, 8.64)	4	(2.9)	4	9	(6.5)	11
Lacrimation increased											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Exposure keratitis											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	1
Atopic keratoconjunctivitis											
Total	Not est.	0.3279			0.7 (-.69, 2.11)	0	(0.0)	0	1	(0.7)	1
Conjunctivitis allergic											
Total	0.6669	0.5286	1.48 (0.43, 5.11)	1.50 (0.42, 5.40)	1.4 (-3.0, 5.88)	4	(2.9)	4	6	(4.3)	8
Infections and infestations											
Any											
Total	0.6669	0.5286	1.49 (0.43, 5.24)	1.51 (0.42, 5.49)	1.4 (-3.0, 5.84)	4	(2.9)	5	6	(4.3)	6

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

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Table 1.17.714.4.1: Total, Any TEAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%) E	Tralokinumab Q2W + TCS n (%) E
Herpes ophthalmic							
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7) 1	0 (0.0) 0
Keratitis viral							
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7) 1	0 (0.0) 0
Conjunctivitis							
Total	0.7410	0.1591	2.96 (0.61, 14.5)	3.05 (0.60, 15.4)	2.9 (-1.1, 6.81)	2 (1.5) 3	6 (4.3) 6

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 1.17.715.4.1: Total, Any TESAESI - Eye disorders (conjunctivitis, keratoconjunctivitis, and keratitis) by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Not using RDCSA					36	17.1		33	16.3	
Using RDCSA					101	48.3		105	49.1	

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 1.17.716.4.1: Total, Any TEAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	2
Using RDCSA		0.3173			1.0 (-.90, 2.85)	0	(0.0)	0	1	(1.0)	2
Infections and infestations											
Any											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	2
Eczema herpeticum											
Total	Not est.	0.3103			0.7 (-.69, 2.17)	0	(0.0)	0	1	(0.7)	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 1.17.717.4.1: Total, Any TESAESI - Eczema herpeticum by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Not using RDCSA					36	17.1		33	16.3	
Using RDCSA					101	48.3		105	49.1	

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 1.17.718.4.1: Total, Any TEAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Not using RDCSA					36	17.1		33	16.3	
Using RDCSA					101	48.3		105	49.1	

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 1.17.719.4.1: Total, Any TESAESI - Malignancies by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Not using RDCSA					36	17.1		33	16.3	
Using RDCSA					101	48.3		105	49.1	

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 1.17.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Not using RDCSA						36 17.1		33 16.3	
Using RDCSA						101 48.3		105 49.1	
Any system organ class									
Any preferred term									
Total	0.3672	0.0178	0.12 (0.02, 0.99)	0.12 (0.01, 0.96)	-5.1 (-9.3, -.93)	8 (5.8)	12	1 (0.7)	1
Not using RDCSA		0.0950	0.00 (not est.)	0.00 (not est.)	-8.3 (-17, 0.71)	3 (8.3)	3	0 (0.0)	0
Using RDCSA		0.0898	0.19 (0.02, 1.64)	0.18 (0.02, 1.61)	-4.0 (-8.6, 0.62)	5 (5.0)	9	1 (1.0)	1
Infections and infestations									
Any									
Total	0.3266	0.0311	0.14 (0.02, 1.15)	0.13 (0.02, 1.12)	-4.4 (-8.3, -.44)	7 (5.1)	11	1 (0.7)	1
Not using RDCSA		0.0950	0.00 (not est.)	0.00 (not est.)	-8.3 (-17, 0.71)	3 (8.3)	3	0 (0.0)	0
Using RDCSA		0.1604	0.24 (0.03, 2.12)	0.23 (0.02, 2.11)	-3.0 (-7.3, 1.20)	4 (4.0)	8	1 (1.0)	1
Cellulitis									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Wound infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Oral herpes									
Total	Not est.	0.3067	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.2, 0.70)	1 (0.7)	1	0 (0.0)	0
Staphylococcal skin infection									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Dermatitis infected									
Total	0.2922	0.1718	0.24 (0.03, 2.19)	0.24 (0.03, 2.19)	-2.2 (-5.4, 0.94)	4 (2.9)	7	1 (0.7)	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

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Table 1.17.720.4.1: Total, Any TEAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Skin and subcutaneous tissue disorders									
Any									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	1	0 (0.0)	0
Hand dermatitis									
Total	Not est.	0.3243	0.00 (not est.)	0.00 (not est.)	-0.7 (-2.1, 0.70)	1 (0.7)	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 1.17.721.4.1: Total, Any TESAESI - Skin infections requiring systemic treatment by SOC and PT treatment comparison, LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Total					137	65.4		138	65.4	
Not using RDCSA					36	17.1		33	16.3	
Using RDCSA					101	48.3		105	49.1	

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 1.17.722.4.1: Total, Any TEAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n	Placebo + TCS (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n	Tralokinumab Q2W + TCS (%)	Tralokinumab Q2W + TCS E
Analysis set											
N, Exposure(years)											
Total						137	65.4		138	65.4	
Not using RDCSA						36	17.1		33	16.3	
Using RDCSA						101	48.3		105	49.1	
Any system organ class											
Any preferred term											
Total	0.2972	0.8030	0.98 (0.87, 1.12)	0.93 (0.53, 1.64)	-1.3 (-11, 8.62)	107	(78.1)	391	106	(76.8)	361
Not using RDCSA		0.3026	0.86 (0.64, 1.15)	0.57 (0.19, 1.66)	-11 (-32, 9.75)	28	(77.8)	107	22	(66.7)	56
Using RDCSA		0.7395	1.02 (0.89, 1.18)	1.12 (0.57, 2.20)	1.9 (-9.2, 13.0)	79	(78.2)	284	84	(80.0)	305

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 1.17.723.4.1: Total, Any TE SAE (not including Dermatitis atopic and Pruritus), LP0162-1346, 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 + TCS n (%)	Placebo + TCS E	Tralokinumab Q2W + TCS n (%)	Tralokinumab Q2W + TCS E
Analysis set									
N, Exposure(years)									
Total						137 65.4		138 65.4	
Not using RDCSA						36 17.1		33 16.3	
Using RDCSA						101 48.3		105 49.1	
Any system organ class									
Any preferred term									
Total	0.3574	0.1007	0.20 (0.02, 1.68)	0.20 (0.02, 1.70)	-2.9 (-6.3, 0.54)	5 (3.6)	8	1 (0.7)	1
Not using RDCSA		0.1753	0.00 (not est.)	0.00 (not est.)	-5.6 (-13, 1.92)	2 (5.6)	3	0 (0.0)	0
Using RDCSA		0.3045	0.33 (0.04, 3.05)	0.32 (0.03, 3.14)	-2.0 (-5.8, 1.81)	3 (3.0)	5	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. TE SAE: Treatment emergent serious adverse events. The preferred term Dermatitis atopic and the higher level term: Pruritus NEC are excluded.

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