Clinical trial results:
An open-label, single-arm, multi-centre, long-term extension trial to evaluate the safety and efficacy of tralokinumab in subjects with atopic dermatitis who participated in previous tralokinumab clinical trials

Summary

EudraCT number	2018-000746-19
Trial protocol	ES GB DE PL BE CZ IT
Global end of trial date	03 July 2024

Results information

Result version number	v1 (current)
This version publication date	05 January 2025
First version publication date	05 January 2025

Trial information

Trial identification

Sponsor protocol code	LP0162-1337

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03587805
WHO universal trial number (UTN)	U1111-1282-4519

Notes:

Sponsors

Sponsor organisation name	LEO Pharma A/S
Sponsor organisation address	Industriparken 55, Ballerup, Denmark, 2750
Public contact	Clinical disclosure, Leo Pharma A/S, +45 4494 5888, disclosure@leo-pharma.com
Scientific contact	Clinical disclosure, Leo Pharma A/S, +45 4494 5888, disclosure@leo-pharma.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 July 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 July 2024
Global end of trial reached?	Yes
Global end of trial date	03 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term safety of tralokinumab

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH GCP), including archiving of essential documents.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 August 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 237
Country: Number of subjects enrolled	Japan: 181
Country: Number of subjects enrolled	United States: 384
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	Poland: 228
Country: Number of subjects enrolled	Spain: 127
Country: Number of subjects enrolled	United Kingdom: 70
Country: Number of subjects enrolled	Belgium: 69
Country: Number of subjects enrolled	Czechia: 20
Country: Number of subjects enrolled	France: 73
Country: Number of subjects enrolled	Germany: 268
Worldwide total number of subjects	1672
EEA total number of subjects	870

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	103
Adults (18-64 years)	1498
From 65 to 84 years	70
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

This trial was conducted at 309 sites that screened subjects in 11 countries.

Pre-assignment

Screening details:

1706 subjects screened for this trial, 34 subjects were excluded prior to treatment assignment.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	tralokinumab

Arm description:

Week 0: subcutaneous (SC) injection of tralokinumab loading dose. From Week 2 up to Week 266*: SC injection of tralokinumab maintenance dose.
*The length of treatment for each subject will depend on when they enter the trial, and on which parent trial and country they come from.
Tralokinumab: Human recombinant monoclonal antibody of the IgG4 subclass that specifically binds to human IL-13 and blocks interaction with the IL-13 receptors. Presented as a liquid formulation for subcutaneous
injection.

Arm type	Experimental
Investigational medicinal product name	Tralokinumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dose for adult subjects from all parent trials, except the parent trial LP0162-1334: 600 mg initial loading dose, then 300 mg every second week.
Dose for subjects from the parent trial LP0162-1334: 300 mg every second week.

Number of subjects in period 1	tralokinumab
Started	1672
Completed	1143
Not completed	529
Adverse event, serious fatal	1
COVID-19 pandemic	4
Consent withdrawn by subject	105
Adverse event, non-fatal	72
Reason unknown	26
Various reasons	121

Lost to follow-up	78
Withdrawal by parent/guardian	3
Lack of efficacy	119

Baseline characteristics

Reporting groups	
Reporting group title	Overall study

Reporting group description: -

Reporting group values	Overall study	Total	
Number of subjects	1672	1672	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	103	103	
Adults (18-64 years)	1498	1498	
From 65-84 years	70	70	
85 years and over	1	1	
Age continuous Units: years			
arithmetic mean	37.5		
standard deviation	± 14.8	-	
Gender categorical Units: Subjects			
Female	709	709	
Male	963	963	
Race Units: Subjects			
White	1194	1194	
Black or African American	120	120	
Asian	312	312	
American Indian or Alaska Native	2	2	
Native Hawaiian or other Pacific Islander	4	4	
Other	38	38	
Missing	2	2	
Ethnicity Units: Subjects			
Hispanic or Latino	112	112	
Not Hispanic or Latino	1558	1558	
Unknown or Not Reported	2	2	
Weight Units: kg			
arithmetic mean	77.1		
standard deviation	± 19.1	-	
Height Units: cm			

arithmetic mean	170.3		
standard deviation	± 10.1	-	
BMI			
Units: kg/m^2			
arithmetic mean	26.52		
standard deviation	± 6.04	-	

End points

End points reporting groups

Reporting group title	tralokinumab

Reporting group description:

Week 0: subcutaneous (SC) injection of tralokinumab loading dose. From Week 2 up to Week 266*: SC injection of tralokinumab maintenance dose.
*The length of treatment for each subject will depend on when they enter the trial, and on which parent trial and country they come from.
Tralokinumab: Human recombinant monoclonal antibody of the IgG4 subclass that specifically binds to human IL-13 and blocks interaction with the IL-13 receptors. Presented as a liquid formulation for subcutaneous
injection.

Primary: Number of adverse events from baseline through the last treatment visit (up to Week 268)

End point title	Number of adverse events from baseline through the last treatment visit (up to Week 268)[1]

End point description:

End point type	Primary

End point timeframe:

From Week 0 up to Week 268

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis as the primary endpoint is investigating safety.

End point values	tralokinumab			
Subject group type	Reporting group			
Number of subjects analysed	1672			
Units: events	8119			

Statistical analyses

No statistical analyses for this end point

Secondary: Investigator’s Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) at Weeks 16, 56, 88, 104, 136, 152, 184, 216, and 248

End point title	Investigator’s Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) at Weeks 16, 56, 88, 104, 136, 152, 184, 216, and 248

End point description:

The IGA is an instrument used in clinical trials to rate the severity of the subject's global atopic dermatitis and is based on a 5-point scale ranging from 0 (clear) to 4 (severe).

End point type	Secondary

End point timeframe:

From Week 16 up to Week 248

End point values	tralokinumab			
Subject group type	Reporting group			
Number of subjects analysed	1647			
Units: percentage of responders				
number (confidence interval 95%)				
IGA 0/1 at Week 16	47.3 (44.9 to 49.8)			
IGA 0/1 at Week 56	48.5 (45.9 to 51.1)			
IGA 0/1 at Week 88	48.6 (46.1 to 51.1)			
IGA 0/1 at Week 104	47.1 (44.6 to 49.6)			
IGA 0/1 at Week 136	48.7 (46.2 to 51.3)			
IGA 0/1 at Week 152	46.8 (44.1 to 49.4)			
IGA 0/1 at Week 184	46.7 (44.1 to 49.3)			
IGA 0/1 at Week 216	47.2 (44.4 to 50.0)			
IGA 0/1 at Week 248	46.9 (44.1 to 49.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: At least 75% reduction in Eczema Area and Severity Index (EASI75) relative to baseline in parent trial, at Weeks 16, 56, 88, 104, 136, 152, 184, 216, and 248

End point title	At least 75% reduction in Eczema Area and Severity Index (EASI75) relative to baseline in parent trial, at Weeks 16, 56, 88, 104, 136, 152, 184, 216, and 248

End point description:

The EASI is a validated measure used in clinical practice and clinical trials to assess the severity and extent of atopic dermatitis. The EASI is a composite index with scores ranging from 0 to 72, with higher values indicating more severe or more extensive condition.

End point type	Secondary

End point timeframe:

From Week 16 up to Week 248

End point values	tralokinumab			
Subject group type	Reporting group			
Number of subjects analysed	1639			
Units: percentage of responders				
number (confidence interval 95%)				
EASI75 at Week 16	77.0 (74.9 to 79.0)			
EASI75 at Week 56	75.2 (72.9 to 77.4)			
EASI75 at Week 88	75.1 (72.9 to 77.3)			
EASI75 at Week 104	74.6 (72.3 to 76.8)			
EASI75 at Week 136	74.1 (71.7 to 76.3)			
EASI75 at Week 152	73.0 (70.6 to 75.2)			
EASI75 at Week 184	72.3 (69.7 to 74.6)			
EASI75 at Week 216	72.1 (69.7 to 74.5)			
EASI75 at Week 248	71.7 (69.2 to 74.1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline up to week 268

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27

Reporting groups

Reporting group title	tralokinumab

Reporting group description:

Week 0: subcutaneous (SC) injection of tralokinumab loading dose. From Week 2 up to Week 266: SC injection of tralokinumab maintenance dose. The length of treatment for each subject will depend on when they enter the trial, and on which parent trial and country they come from. Tralokinumab: Human recombinant monoclonal antibody of the IgG4 subclass that specifically binds to human IL-13 and blocks interaction with the IL-13 receptors. Presented as a liquid formulation for subcutaneous injection.

Serious adverse events	tralokinumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	151 / 1672 (9.03%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenoid cystic carcinoma			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	2 / 1672 (0.12%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Cutaneous T-cell lymphoma			
subjects affected / exposed	2 / 1672 (0.12%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 1		
Invasive breast carcinoma			

subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Invasive ductal breast carcinoma			
subjects affected / exposed	2 / 1672 (0.12%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma in situ			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian cancer			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Papillary thyroid cancer			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Tonsil cancer			

subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral artery thrombosis			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Alcohol detoxication			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac resynchronisation therapy			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Ruptured ectopic pregnancy			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Adverse drug reaction			

subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	4 / 1672 (0.24%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Corneal graft rejection			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Endometriosis			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	3 / 1672 (0.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			

subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Obstructive sleep apnoea syndrome				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Acute psychosis				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Alcohol withdrawal syndrome				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bipolar disorder				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Irritability				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Major depression				

subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychotic disorder				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Schizophrenia				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Suicidal ideation				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Suicide attempt				
subjects affected / exposed	2 / 1672 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Product issues				
Device dislocation				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Investigations				
Blood creatinine increased				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Alcohol poisoning				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Ankle fracture				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cartilage injury				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clavicle fracture				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Craniocerebral injury				
subjects affected / exposed	3 / 1672 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural complication				
subjects affected / exposed	2 / 1672 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				

subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post-traumatic neck syndrome				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Seroma				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Wrist fracture				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Atrial septal defect				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Corneal dystrophy				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute myocardial infarction				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

Angina pectoris			
subjects affected / exposed	2 / 1672 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	2 / 1672 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial tachycardia			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery occlusion			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	3 / 1672 (0.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			

subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pericarditis				
subjects affected / exposed	2 / 1672 (0.12%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Encephalopathy				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	2 / 1672 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Migraine with aura				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Multiple sclerosis				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Radiculopathy				

subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
Vertigo				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Atopic cataract				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cataract				
subjects affected / exposed	3 / 1672 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Cataract nuclear				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Corneal disorder				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Glaucoma				

subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Retinal detachment				
subjects affected / exposed	2 / 1672 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ulcerative keratitis				
subjects affected / exposed	2 / 1672 (0.12%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Vitreous haemorrhage				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vogt-Koyanagi-Harada disease				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Colitis ulcerative				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Crohn disease				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemoperitoneum				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				

subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Proctitis ulcerative			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Atopic dermatitis			
subjects affected / exposed	12 / 1672 (0.72%)		
occurrences causally related to treatment / all	1 / 12		
deaths causally related to treatment / all	0 / 0		
Cutaneous vasculitis			

subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermatitis psoriasiform			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Bladder metaplasia			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	2 / 1672 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Proteinuria			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ureterolithiasis			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Foot deformity			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
intervertebral disc protusion			
subjects affected / exposed	3 / 1672 (0.18%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		

Jaw cyst				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal osteoarthritis				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tenosynovitis				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Appendicitis				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Appendicitis perforated				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthritis bacterial				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthritis infective				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Colonic abscess				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
COVID-19				

subjects affected / exposed	5 / 1672 (0.30%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Dermatitis infected				
subjects affected / exposed	2 / 1672 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eczema herpeticum				
subjects affected / exposed	3 / 1672 (0.18%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Encephalitis herpes				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endocarditis				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Giardiasis				
subjects affected / exposed	1 / 1672 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster pharyngitis				

subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infectious mononucleosis			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infectious pleural effusion			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral discitis			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Klebsiella bacteraemia			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Localised infection			
subjects affected / exposed	2 / 1672 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Medical device site joint infection			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonsillar abscess			

subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tonsilitis			
subjects affected / exposed	2 / 1672 (0.12%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	1 / 1672 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	tralokinumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	924 / 1672 (55.26%)		
Nervous system disorders			
Headache			
subjects affected / exposed	114 / 1672 (6.82%)		
occurrences (all)	143		
Skin and subcutaneous tissue disorders			
Atopic dermatitis			
subjects affected / exposed	351 / 1672 (20.99%)		
occurrences (all)	620		
Infections and infestations			
Conjuctivitis			
subjects affected / exposed	103 / 1672 (6.16%)		
occurrences (all)	131		
Covid-19			
subjects affected / exposed	295 / 1672 (17.64%)		
occurrences (all)	317		
Nasopharyngitis			
subjects affected / exposed	372 / 1672 (22.25%)		
occurrences (all)	599		
Upper respiratory tract infection			
subjects affected / exposed	147 / 1672 (8.79%)		
occurrences (all)	233		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 June 2018	The main reason for this amendment is to change an inclusion criterion that will enable all eligible subjects to enter this trial directly after completing the treatment period(s) in their parent trial.
31 August 2018	The main reason for this amendment is to change an inclusion criterion to also allow eligible subjects from trial LP0162-1346 to enter the extension trial.
13 December 2018	The main reason for this amendment is to change exclusion criterion to reflect that a wash-out period is not considered necessary because subjects are allowed to resume investigational medicinal product following 5 half-lives after the last administration of systemic immunosuppressive or immunomodulating drugs and/or systemic corticosteroids. Clarifications on how to handle duplicate assessments (i.e. assessments performed on the same day) between parent trial and trial LP0162-1337 have been added.
28 May 2019	The main reason for this amendment is to introduce the option to take skin biopsy samples at selected sites in the subgroup of subjects who had skin biopsy samples in the parent trial LP0162-1325 and to consolidate the 2 screening visits to 1 visit.
17 February 2020	The main reason for the amendment is to introduce the possibility for eligible subjects in selected countries of trial LP0162-1334 with adolescent subjects to continue in this long-term extension trial (LP0162-1337, ECZTEND). The purpose is to obtain long-term safety data for adolescent subjects with atopic dermatitis (AD) treated with tralokinumab.
25 November 2020	The main reason for this amendment is to extend the collection of long-term safety data for tralokinumab up to 5 years, and at the same time provide subjects the possibility to continue treatment until treatment with tralokinumab is also available to patients outside the clinical trial setting. Subjects from the parent trial LP0162-1334 will have the opportunity to continue for an additional 1-year extension, providing an additional year of safety data for adolescents/young adults. To reduce the burden of frequent site visits for subjects, the amendment will introduce a visit schedule more similar to standard practice for home use. The modified design reduces the number of site visits and instead introduces a mandatory telephone visit in between site visits to ensure close safety monitoring of the subjects. This amendment also introduces the possibility for eligible subjects from 2 new parent trials, LP0162-1343 and TRA-WEI-0015-I, to participate in this long-term extension trial.
08 February 2022	The main reason for amendment 9 is to shorten the safety follow-up period from 16 weeks to 4 weeks for subjects transferred from the adolescent parent trial LP0162-1334. Furthermore, changes that were made for the local protocol versions for Japan and Germany have been implemented in the protocol, and the definition of treatment completers has been updated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/35863467

http://www.ncbi.nlm.nih.gov/pubmed/38563683

http://www.ncbi.nlm.nih.gov/pubmed/36223087