



Clinical trial results:

A Multicenter, Open-Label, Extension Trial to Investigate Long Term Efficacy and Safety of Lonapegsomatropin in Adults with Growth Hormone Deficiency

Summary

EudraCT number	2021-004313-39
Trial protocol	GR SK FR ES DE IT RO
Global end of trial date	23 December 2024

Results information

Result version number	v1 (current)
This version publication date	03 January 2026
First version publication date	03 January 2026

Trial information

Trial identification

Sponsor protocol code	TCH-306 EXT
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05171855
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ascendis Pharma
Sponsor organisation address	Tuborg Boulevard 12, Hellerup, Denmark, DK-2900
Public contact	Clinical Trial Information Desk, Ascendis Pharma A/S, 0045 70222244, clinhelpdesk@ascendispharma.com
Scientific contact	Clinical Trial Information Desk, Ascendis Pharma A/S, 0045 70222244, clinhelpdesk@ascendispharma.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	02 September 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety of once-weekly lonapegsomatropin in adults with growth hormone deficiency (GHD) previously treated in trial TCH-306 or switching from commercially available somatropin treatment (Japan only).

Protection of trial subjects:

This trial was conducted in accordance with the ethical principles of Good Clinical Practice, according to the International Conference on Harmonisation Harmonized Tripartite Guideline.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 December 2021
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	Armenia: 5
Country: Number of subjects enrolled	Australia: 10
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	Georgia: 21
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	Korea, Republic of: 3
Country: Number of subjects enrolled	Malaysia: 4
Country: Number of subjects enrolled	Serbia: 3
Country: Number of subjects enrolled	Türkiye: 10
Country: Number of subjects enrolled	Ukraine: 27
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	United States: 41
Country: Number of subjects enrolled	Japan: 28
Country: Number of subjects enrolled	Poland: 37
Country: Number of subjects enrolled	Romania: 2
Country: Number of subjects enrolled	Slovakia: 4
Country: Number of subjects enrolled	Spain: 10
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Greece: 9

Country: Number of subjects enrolled	Italy: 3
Worldwide total number of subjects	233
EEA total number of subjects	75

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)	0
Adults (18-64 years)	233
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study TCH-306 EXT enrolled subjects who had completed treatment in TCH-306 (NCT04615273/2021-004313-39). In Japan only, subjects switched from commercially available somatropin therapy (reported separately).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Lona pegsomatropin/Lona pegsomatropin

Arm description:

Subjects who had completed treatment with lona pegsomatropin in TCH-306 were enrolled in the extension study and received lona pegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.

Arm type	Experimental
Investigational medicinal product name	Lona pegsomatropin
Investigational medicinal product code	
Other name	ACP-011
Pharmaceutical forms	Powder for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection of Lona pegsomatropin once-weekly for 52 weeks.

Arm title	Placebo/Lona pegsomatropin
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Arm description:

Subjects who had completed treatment with placebo in TCH-306 were enrolled in the extension study and received lona pegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.

Arm type	Experimental
Investigational medicinal product name	Lona pegsomatropin
Investigational medicinal product code	
Other name	ACP-011
Pharmaceutical forms	Powder for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection of Lona pegsomatropin once-weekly for 52 weeks.

Arm title	Somatropin/Lona pegsomatropin
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Arm description:

Subjects who had completed treatment with somatropin in TCH-306 were enrolled in the extension study and received lona pegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.

Arm type	Experimental
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Investigational medicinal product name	Lonapegsomatropin
Investigational medicinal product code	
Other name	ACP-011
Pharmaceutical forms	Powder for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subcutaneous injection of Lonapegsomatropin once-weekly for 52 weeks.

Number of subjects in period 1^[1]	Lonapegsomatropin/ Lonapegsomatropin	Placebo/Lonapegsom atropin	Somatropin/Lonapeg somatropin
Started	73	73	74
Completed	67	69	66
Not completed	6	4	8
Consent withdrawn by subject	2	-	5
Physician decision	1	-	-
Adverse event, non-fatal	2	4	2
Death	1	-	-
Unspecified	-	-	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Subjects in the commercial switch arm (Japan only) are reported separately.

Baseline characteristics

Reporting groups

Reporting group title	Lonapegsomatropin/Lonapegsomatropin
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Reporting group description:

Subjects who had completed treatment with lonapegsomatropin in TCH-306 were enrolled in the extension study and received lonapegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.

Reporting group title	Placebo/Lonapegsomatropin
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Reporting group description:

Subjects who had completed treatment with placebo in TCH-306 were enrolled in the extension study and received lonapegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.

Reporting group title	Somatropin/Lonapegsomatropin
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Reporting group description:

Subjects who had completed treatment with somatropin in TCH-306 were enrolled in the extension study and received lonapegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.

Reporting group values	Lonapegsomatropin/ Lonapegsomatropin	Placebo/Lonapegsom atropin	Somatropin/Lonapeg somatropin
Number of subjects	73	73	74
Age categorical Units: Subjects			
< 30 years	10	13	14
>= 30 to <= 60 years	53	51	52
> 60 years	10	9	8
Gender categorical Units: Subjects			
Female	37	32	31
Male	36	41	43
Ethnicity Units: Subjects			
Hispanic or Latino	3	3	5
Not Hispanic or Latino	68	69	67
Unknown or Not Reported	2	1	2
Race Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	9	7	8
Black or African American	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	59	62	64
Other	5	3	1

Reporting group values	Total		
Number of subjects	220		
Age categorical Units: Subjects			
< 30 years	37		

>= 30 to <= 60 years	156		
> 60 years	27		
Gender categorical			
Units: Subjects			
Female	100		
Male	120		
Ethnicity			
Units: Subjects			
Hispanic or Latino	11		
Not Hispanic or Latino	204		
Unknown or Not Reported	5		
Race			
Units: Subjects			
American Indian or Alaska Native	1		
Asian	24		
Black or African American	1		
Native Hawaiian or Other Pacific Islander	0		
White	185		
Other	9		

End points

End points reporting groups

Reporting group title	Lonapegsomatropin/Lonapegsomatropin
Reporting group description: Subjects who had completed treatment with lonapegsomatropin in TCH-306 were enrolled in the extension study and received lonapegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.	
Reporting group title	Placebo/Lonapegsomatropin
Reporting group description: Subjects who had completed treatment with placebo in TCH-306 were enrolled in the extension study and received lonapegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.	
Reporting group title	Somatropin/Lonapegsomatropin
Reporting group description: Subjects who had completed treatment with somatropin in TCH-306 were enrolled in the extension study and received lonapegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.	

Primary: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), Serious TEAEs and TEAE Leading to Study Discontinuation

End point title	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), Serious TEAEs and TEAE Leading to Study Discontinuation ^[1]
End point description: An Adverse Event (AE) was defined as any untoward medical occurrence in a clinical investigation participant administered a pharmaceutical product and which does not necessarily have a causal relationship with the treatment. An AE was considered a TEAE if it occurred on or after the first dose of investigational product and was not present prior to the first dose, or it was present at the first dose but increased in severity during the trial. A serious AE was any untoward medical occurrence at any dose that met any of the following criteria: resulted in death; was life threatening; required or prolonged inpatient hospitalisation; resulted in persistent or significant disability/incapacity; resulted in a congenital anomaly/birth defect in a neonate/infant born to a mother exposed or was considered a significant medical event by the investigator. Analysis was performed on all subjects who were exposed to any amount of the trial drug in the study TCH306 EXT.	
End point type	Primary
End point timeframe: Up to 52 Weeks	

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 data was reported for this endpoint as the endpoint was descriptive in nature.

End point values	Lonapegsomatropin/Lonapegsomatropin	Placebo/Lonapegsomatropin	Somatropin/Lonapegsomatropin	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	73	74	
Units: subjects				
TEAEs	48	52	45	
Serious TEAEs	7	4	5	
TEAE Leading to Study Discontinuation	2	4	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Trunk Percent Fat at Week 52

End point title	Change From Baseline in Trunk Percent Fat at Week 52
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End point description:

Trunk percent fat was assessed by dual-energy X-ray absorptiometry. Analysis was performed on safety analysis set. Here, "number analysed" = subjects with available data for this endpoint.

End point type	Secondary
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End point timeframe:

Baseline main trial to week 52 (extension period)

End point values	Lonapegsomatropin/Lonapegsomatropin	Placebo/Lonapegsomatropin	Somatropin/Lonapegsomatropin	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	69	66	
Units: percent fat				
least squares mean (confidence interval 95%)	-1.21 (-2.41 to -0.01)	-1.60 (-2.35 to -0.86)	-1.11 (-2.05 to -0.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Trunk Fat Mass at Week 52

End point title	Change From Baseline in Trunk Fat Mass at Week 52
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End point description:

Trunk fat mass was assessed by dual-energy X-ray absorptiometry. Analysis was performed on safety analysis set. Here, "number analysed" = subjects with available data for this endpoint.

End point type	Secondary
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End point timeframe:

Baseline main trial to week 52 (extension period)

End point values	Lonapegsomatropin/Lonapegsomatropin	Placebo/Lonapegsomatropin	Somatropin/Lonapegsomatropin	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	69	66	
Units: kilogram(s)				
least squares mean (confidence interval 95%)	0.15 (-0.47 to 0.77)	-0.16 (-0.63 to 0.31)	-0.00 (-0.53 to 0.53)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Body Lean Mass at Week 52

End point title	Change From Baseline in Total Body Lean Mass at Week 52
End point description: Total body lean mass was assessed by dual-energy X-ray absorptiometry. Analysis was performed on safety analysis set. Here, "number analysed" = subjects with available data for this endpoint.	
End point type	Secondary
End point timeframe: Baseline main trial to week 52 (extension period)	

End point values	Lonapegsomatropin/Lonapegsomatropin	Placebo/Lonapegsomatropin	Somatropin/Lonapegsomatropin	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	67	69	66	
Units: kilogram(s)				
least squares mean (confidence interval 95%)	2.26 (1.47 to 3.05)	1.97 (1.15 to 2.80)	2.07 (1.21 to 2.94)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of the study drug up to Week 52

Adverse event reporting additional description:

Analysis was performed on all subjects who were exposed to any amount of the trial drug in the study TCH306 EXT.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.0
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Reporting groups

Reporting group title	Lonapegsomatropin/Lonapegsomatropin
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Reporting group description:

Subjects who had completed treatment with lonapegsomatropin in TCH-306 were enrolled in the extension study and received lonapegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.

Reporting group title	Placebo/Lonapegsomatropin
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Reporting group description:

Subjects who had completed treatment with placebo in TCH-306 were enrolled in the extension study and received lonapegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.

Reporting group title	Somatropin/Lonapegsomatropin
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Reporting group description:

Subjects who had completed treatment with somatropin in TCH-306 were enrolled in the extension study and received lonapegsomatropin administered once weekly by subcutaneous injection for a treatment period of up to 52 weeks.

Serious adverse events	Lonapegsomatropin/ Lonapegsomatropin	Placebo/Lonapegsom atropin	Somatropin/Lonapeg somatropin
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 73 (9.59%)	4 / 73 (5.48%)	5 / 74 (6.76%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pituitary tumour benign			
subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	0 / 73 (0.00%)	1 / 73 (1.37%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Cerebral cyst			
subjects affected / exposed	0 / 73 (0.00%)	0 / 73 (0.00%)	1 / 74 (1.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Multiple sclerosis relapse			
subjects affected / exposed	0 / 73 (0.00%)	0 / 73 (0.00%)	1 / 74 (1.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 73 (0.00%)	1 / 73 (1.37%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sarcoidosis of lymph node			
subjects affected / exposed	0 / 73 (0.00%)	0 / 73 (0.00%)	1 / 74 (1.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 73 (0.00%)	1 / 73 (1.37%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 73 (0.00%)	1 / 73 (1.37%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			

subjects affected / exposed	0 / 73 (0.00%)	1 / 73 (1.37%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary mass			
subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenocortical insufficiency acute			
subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			
subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Spinal osteoarthritis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 73 (0.00%)	1 / 74 (1.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Clostridium difficile colitis			

subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected seroma			
subjects affected / exposed	0 / 73 (0.00%)	0 / 73 (0.00%)	1 / 74 (1.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Norovirus infection			
subjects affected / exposed	1 / 73 (1.37%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 73 (2.74%)	0 / 73 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Lonapegsomatropin/ Lonapegsomatropin	Placebo/Lonapegsom atropin	Somatropin/Lonapeg somatropin
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 73 (34.25%)	29 / 73 (39.73%)	21 / 74 (28.38%)
Investigations			
Haematocrit increased			
subjects affected / exposed	0 / 73 (0.00%)	5 / 73 (6.85%)	1 / 74 (1.35%)
occurrences (all)	0	5	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 73 (0.00%)	6 / 73 (8.22%)	4 / 74 (5.41%)
occurrences (all)	0	7	11
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 73 (0.00%)	4 / 73 (5.48%)	1 / 74 (1.35%)
occurrences (all)	0	5	1
Headache			

subjects affected / exposed occurrences (all)	5 / 73 (6.85%) 6	5 / 73 (6.85%) 5	4 / 74 (5.41%) 6
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 73 (1.37%) 1	4 / 73 (5.48%) 8	0 / 74 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	1 / 73 (1.37%) 1	0 / 73 (0.00%) 0	4 / 74 (5.41%) 6
Influenza subjects affected / exposed occurrences (all)	0 / 73 (0.00%) 0	6 / 73 (8.22%) 10	0 / 74 (0.00%) 0
Gastrointestinal disorders Gastroenteritis subjects affected / exposed occurrences (all)	2 / 73 (2.74%) 2	5 / 73 (6.85%) 5	1 / 74 (1.35%) 1
Respiratory, thoracic and mediastinal disorders Upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 73 (9.59%) 11	7 / 73 (9.59%) 11	8 / 74 (10.81%) 8
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	2 / 73 (2.74%) 4	5 / 73 (6.85%) 11	1 / 74 (1.35%) 1
Back pain subjects affected / exposed occurrences (all)	2 / 73 (2.74%) 3	5 / 73 (6.85%) 5	2 / 74 (2.70%) 2
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	4 / 73 (5.48%) 4	4 / 73 (5.48%) 4	2 / 74 (2.70%) 2
Nasopharyngitis subjects affected / exposed occurrences (all)	12 / 73 (16.44%) 17	6 / 73 (8.22%) 10	2 / 74 (2.70%) 2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 February 2022	The rationale of this protocol version was the introduction of two additional exclusion criteria in the event a subject enrolled in Study TCH-306 develops new onset renal and/or hepatic impairment in all countries.
16 June 2022	The rationale of this protocol version was to update safety including anaphylaxis precautions, prohibited medication, precaution if MRI/CT scan were performed at the same visit as DXA scan and correction of typographic errors.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported