Clinical trial results:
A Multinational, Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy, Pharmacokinetics, Pharmacodynamics, Safety, Tolerability, and Immunogenicity of TEV-45779 Compared to Omalizumab (XOLAIR®) in Patients with Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria who Remain Symptomatic Despite Antihistamine (H1) Treatment

Summary

EudraCT number	2021-001796-17
Trial protocol	SK CZ PL GR BG
Global end of trial date	05 April 2024

Results information

Result version number	v1 (current)
This version publication date	12 April 2025
First version publication date	12 April 2025

Trial information

Trial identification

Sponsor protocol code	TV45779-IMB-30086

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04976192
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Teva Branded Pharmaceutical Products R&D, Inc.
Sponsor organisation address	145 Brandywine Parkway, West Chester, United States, 19380
Public contact	Director, Clinical Research, Teva Pharmaceuticals, Inc., MedInfo@tevaeu.com
Scientific contact	Director, Clinical Research, Teva Pharmaceuticals, Inc., MedInfo@tevaeu.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	25 July 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 April 2024
Global end of trial reached?	Yes
Global end of trial date	05 April 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the trial was to demonstrate biosimilar efficacy of TEV-45779 high dose compared to XOLAIR high dose as determined by change in itch severity score of chronic idiopathic urticaria (CIU)/chronic spontaneous urticaria (CSU) in participants who remain symptomatic despite antihistamine (H1) treatment.

Protection of trial subjects:

This trial was conducted in full accordance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Harmonized Tripartite Guideline, Guideline for Good Clinical Practice (GCP) E6, any applicable national and local laws and regulations; Code of Federal Regulations (CFR) Title 21 Parts 11, 50, 54, 56, 312, and 314; European Union (EU) Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws; regulations and administrative provisions of the Member States relating to the implementation of GCP in the conduct of clinical trials on medicinal products for human use.

Background therapy:

Throughout the entire trial, participants remained on a single H1 antihistamine at stable and fixed doses not exceeding label recommendations as the uniform standard treatment regimen.

Evidence for comparator: -

Actual start date of recruitment	07 December 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 8
Country: Number of subjects enrolled	Bulgaria: 72
Country: Number of subjects enrolled	Czechia: 8
Country: Number of subjects enrolled	Georgia: 54
Country: Number of subjects enrolled	Greece: 8
Country: Number of subjects enrolled	Hungary: 19
Country: Number of subjects enrolled	India: 52
Country: Number of subjects enrolled	Korea, Republic of: 78
Country: Number of subjects enrolled	Mexico: 70
Country: Number of subjects enrolled	Poland: 107
Country: Number of subjects enrolled	Slovakia: 12
Country: Number of subjects enrolled	Taiwan: 78
Country: Number of subjects enrolled	United States: 42

Worldwide total number of subjects	608
EEA total number of subjects	226

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)	560
From 65 to 84 years	48
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study included a 24-week treatment period consisting of a 12-week double-blind main treatment period and a 12-week double-blind transition period, which was followed by a 16-week follow-up period.

Period 1

Period 1 title	Main Treatment Period (12 Weeks)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Main Treatment Period: TEV-45779 High Dose

Arm description:

Participants received TEV-45779 subcutaneous (SC) injection at a high dose level every 4 weeks (Q4W) at Weeks 0, 4, and 8.

Arm type	Experimental
Investigational medicinal product name	TEV-45779
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TEV-45779 was administered per schedule specified in the arm description.

Arm title	Main Treatment Period: TEV-45779 Low Dose

Arm description:

Participants received TEV-45779 SC injection at a low dose level Q4W at Weeks 0, 4, and 8.

Arm type	Experimental
Investigational medicinal product name	TEV-45779
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TEV-45779 was administered per schedule specified in the arm description.

Arm title	Main Treatment Period: XOLAIR High Dose

Arm description:

Participants received XOLAIR SC injection at a high dose level Q4W at Weeks 0, 4, and 8.

Arm type	Active comparator
Investigational medicinal product name	XOLAIR®
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

XOLAIR was administered per schedule specified in the arm description.

Arm title	Main Treatment Period: XOLAIR Low Dose

Arm description:

Participants received XOLAIR SC injection at a low dose level Q4W at Weeks 0, 4, and 8.

Arm type	Active comparator
Investigational medicinal product name	XOLAIR®
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

XOLAIR was administered per schedule specified in the arm description.

Number of subjects in period 1	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose
Started	201	102	203
Received at Least 1 Dose of Study Drug	201	102	203
Completed	188	98	194
Not completed	13	4	9
Consent withdrawn by subject	12	3	8
Other Than Specified	1	-	1
Adverse event, non-fatal	-	1	-

Number of subjects in period 1	Main Treatment Period: XOLAIR Low Dose
Started	102
Received at Least 1 Dose of Study Drug	102
Completed	101
Not completed	1
Consent withdrawn by subject	1
Other Than Specified	-
Adverse event, non-fatal	-

Period 2

Period 2 title	Transition Treatment Period (12 Weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Transition Period: TEV-45779/TEV-45779 High Dose

Arm description:

Participants who received TEV-45779 SC injection at a high dose level in the main treatment period, continued to receive TEV-45779 at the same dose level at Weeks 12, 16, and 20 in the transition period.

Arm type	Experimental
Investigational medicinal product name	TEV-45779
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TEV-45779 was administered per schedule specified in the arm description.

Arm title	Transition Period: TEV-45779/TEV-45779 Low Dose

Arm description:

Participants who received TEV-45779 SC injection at a low dose level in the main treatment period, continued to receive TEV-45779 at the same dose level at Weeks 12, 16, and 20 in the transition period.

Arm type	Experimental
Investigational medicinal product name	TEV-45779
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TEV-45779 was administered per schedule specified in the arm description.

Arm title	Transition Period: XOLAIR/XOLAIR High Dose

Arm description:

Participants who received XOLAIR SC injection at a high dose level in the main treatment period, continued to receive XOLAIR at the same dose level at Weeks 12, 16, and 20 in the transition period.

Arm type	Active comparator
Investigational medicinal product name	XOLAIR®
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

XOLAIR was administered per schedule specified in the arm description.

Arm title	Transition Period: XOLAIR/XOLAIR Low Dose

Arm description:

Participants who received XOLAIR SC injection at a low dose level in the main treatment period, continued to receive XOLAIR at the same dose level at Weeks 12, 16, and 20 in the transition period.

Arm type	Active comparator

Investigational medicinal product name	XOLAIR®
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

XOLAIR was administered per schedule specified in the arm description.

Arm title	Transition Period: XOLAIR/TEV-45779 High Dose

Arm description:

Participants who received XOLAIR SC injection at a high dose level in the main treatment period, received TEV-45779 SC injection at a high dose level at Weeks 12, 16, and 20 in the transition period.

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

Dosage and administration details:

XOLAIR was administered per schedule specified in the arm description.

Investigational medicinal product name	TEV-45779
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TEV-45779 was administered per schedule specified in the arm description.

Arm title	Transition Period: XOLAIR/TEV-45779 Low Dose

Arm description:

Participants who received XOLAIR SC injection at a low dose level in the main treatment period, received TEV-45779 SC injection at a low dose level at Weeks 12, 16, and 20 in the transition period.

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

Dosage and administration details:

XOLAIR was administered per schedule specified in the arm description.

Investigational medicinal product name	TEV-45779
Investigational medicinal product code	
Other name	Omalizumab
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TEV-45779 was administered per schedule specified in the arm description.

Number of subjects in period 2	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose
Started	188	98	97
Received at Least 1 Dose of Study Drug	188	98	97
Completed	178	90	93
Not completed	10	8	4
Consent withdrawn by subject	9	7	4
Other Than Specified	1	-	-
Lost to follow-up	-	1	-

Number of subjects in period 2	Transition Period: XOLAIR/XOLAIR Low Dose	Transition Period: XOLAIR/TEV-45779 High Dose	Transition Period: XOLAIR/TEV-45779 Low Dose
Started	51	97	50
Received at Least 1 Dose of Study Drug	51	97	50
Completed	49	95	47
Not completed	2	2	3
Consent withdrawn by subject	2	2	3
Other Than Specified	-	-	-
Lost to follow-up	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Main Treatment Period: TEV-45779 High Dose
Reporting group description:	
Participants received TEV-45779 subcutaneous (SC) injection at a high dose level every 4 weeks (Q4W) at Weeks 0, 4, and 8.	
Reporting group title	Main Treatment Period: TEV-45779 Low Dose
Reporting group description:	
Participants received TEV-45779 SC injection at a low dose level Q4W at Weeks 0, 4, and 8.	
Reporting group title	Main Treatment Period: XOLAIR High Dose
Reporting group description:	
Participants received XOLAIR SC injection at a high dose level Q4W at Weeks 0, 4, and 8.	
Reporting group title	Main Treatment Period: XOLAIR Low Dose
Reporting group description:	
Participants received XOLAIR SC injection at a low dose level Q4W at Weeks 0, 4, and 8.	

Reporting group values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose
Number of subjects	201	102	203
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	41.1	42.7	42.0
standard deviation	± 14.30	± 13.64	± 13.75
Gender Categorical Units: Subjects			
Female	132	69	138
Male	69	33	65
Ethnicity Units: Subjects			
Hispanic/Latino	45	13	26
Not Hispanic/Latino	153	88	174
Unknown	3	0	2
Not Reported	0	1	1
Race Units: Subjects			
American Indian/Alaskan/Native American	12	4	4
Asian	65	35	75
Black/African American	0	3	2
White	123	59	118
Other/Mixed	1	0	3
Not Reported/Unknown	0	1	1
Weekly Itch Severity Score (ISS7)			
Severity of itch was recorded by participants twice daily in their eDiary, on a scale of 0 (none) to 3 (intense/severe). A weekly score (ISS7) was defined as the sum of available daily itch severity scores in that week, divided by the number of days for which a daily itch severity score was available, multiplied			

by 7. The possible range of weekly score was therefore 0 (best score) to 21 (worst score) with higher scores indicating more severe itching. Number of participants analyzed: 196 for TEV-45779 High Dose; 100 for TEV-45779 Low Dose; 203 for XOLAIR High Dose; and 102 for XOLAIR Low Dose.			
Units: units on a scale			
arithmetic mean	16.26	16.14	16.28
standard deviation	± 3.721	± 3.361	± 3.524

Reporting group values	Main Treatment Period: XOLAIR Low Dose	Total	
Number of subjects	102	608	
Age Categorical			
Units: Subjects			
Age Continuous			
Units: years			
arithmetic mean	41.5		
standard deviation	± 14.29	-	
Gender Categorical			
Units: Subjects			
Female	67	406	
Male	35	202	
Ethnicity			
Units: Subjects			
Hispanic/Latino	11	95	
Not Hispanic/Latino	89	504	
Unknown	0	5	
Not Reported	2	4	
Race			
Units: Subjects			
American Indian/Alaskan/Native American	0	20	
Asian	38	213	
Black/African American	0	5	
White	61	361	
Other/Mixed	2	6	
Not Reported/Unknown	1	3	
Weekly Itch Severity Score (ISS7)			
Severity of itch was recorded by participants twice daily in their eDiary, on a scale of 0 (none) to 3 (intense/severe). A weekly score (ISS7) was defined as the sum of available daily itch severity scores in that week, divided by the number of days for which a daily itch severity score was available, multiplied by 7. The possible range of weekly score was therefore 0 (best score) to 21 (worst score) with higher scores indicating more severe itching. Number of participants analyzed: 196 for TEV-45779 High Dose; 100 for TEV-45779 Low Dose; 203 for XOLAIR High Dose; and 102 for XOLAIR Low Dose.			
Units: units on a scale			
arithmetic mean	16.00		
standard deviation	± 3.723	-	

End points

End points reporting groups

Reporting group title	Main Treatment Period: TEV-45779 High Dose
Reporting group description:	
Participants received TEV-45779 subcutaneous (SC) injection at a high dose level every 4 weeks (Q4W) at Weeks 0, 4, and 8.	
Reporting group title	Main Treatment Period: TEV-45779 Low Dose
Reporting group description:	
Participants received TEV-45779 SC injection at a low dose level Q4W at Weeks 0, 4, and 8.	
Reporting group title	Main Treatment Period: XOLAIR High Dose
Reporting group description:	
Participants received XOLAIR SC injection at a high dose level Q4W at Weeks 0, 4, and 8.	
Reporting group title	Main Treatment Period: XOLAIR Low Dose
Reporting group description:	
Participants received XOLAIR SC injection at a low dose level Q4W at Weeks 0, 4, and 8.	
Reporting group title	Transition Period: TEV-45779/TEV-45779 High Dose
Reporting group description:	
Participants who received TEV-45779 SC injection at a high dose level in the main treatment period, continued to receive TEV-45779 at the same dose level at Weeks 12, 16, and 20 in the transition period.	
Reporting group title	Transition Period: TEV-45779/TEV-45779 Low Dose
Reporting group description:	
Participants who received TEV-45779 SC injection at a low dose level in the main treatment period, continued to receive TEV-45779 at the same dose level at Weeks 12, 16, and 20 in the transition period.	
Reporting group title	Transition Period: XOLAIR/XOLAIR High Dose
Reporting group description:	
Participants who received XOLAIR SC injection at a high dose level in the main treatment period, continued to receive XOLAIR at the same dose level at Weeks 12, 16, and 20 in the transition period.	
Reporting group title	Transition Period: XOLAIR/XOLAIR Low Dose
Reporting group description:	
Participants who received XOLAIR SC injection at a low dose level in the main treatment period, continued to receive XOLAIR at the same dose level at Weeks 12, 16, and 20 in the transition period.	
Reporting group title	Transition Period: XOLAIR/TEV-45779 High Dose
Reporting group description:	
Participants who received XOLAIR SC injection at a high dose level in the main treatment period, received TEV-45779 SC injection at a high dose level at Weeks 12, 16, and 20 in the transition period.	
Reporting group title	Transition Period: XOLAIR/TEV-45779 Low Dose
Reporting group description:	
Participants who received XOLAIR SC injection at a low dose level in the main treatment period, received TEV-45779 SC injection at a low dose level at Weeks 12, 16, and 20 in the transition period.	
Subject analysis set title	TEV-45779 vs XOLAIR
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received TEV-45779 SC injection Q4W at Weeks 0, 4, and 8 in TEV-45779 arms. Participants received XOLAIR SC injection Q4W at Weeks 0, 4, and 8 in XOLAIR arms.	

Primary: Change From Baseline in the ISS7 at Week 12, TEV-45779 High Dose Compared to XOLAIR High Dose (For European Medicines Agency [EMA] Submission)

End point title	Change From Baseline in the ISS7 at Week 12, TEV-45779 High Dose Compared to XOLAIR High Dose (For European Medicines Agency [EMA] Submission)[1]
End point description:	
The severity of the itch was recorded by the participants twice daily in their eDiary, on a scale of 0	

(none) to 3 (intense/severe). A weekly itch score (ISS7) was defined as the sum of the available daily itch severity scores in that week, divided by the number of days for which a daily itch severity score was available, multiplied by 7. The daily ISS was calculated as the average of the morning and evening scores. The possible range of the weekly score was therefore 0 (best score) to 21 (worst score) with higher scores indicating more severe itching. Least square (LS) mean and 95% confidence interval (CI) were calculated using analysis of covariance (ANCOVA) model. The intent-to-treat (ITT) analysis set included all randomized participants.

End point type	Primary

End point timeframe:

Baseline, Week 12

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The reported data is statistical analysis data.

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: XOLAIR High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	201	203		
Units: units on a scale				
least squares mean (confidence interval 95%)	-10.92 (-11.85 to -9.99)	-10.61 (-11.51 to -9.71)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Main Treatment Period: TEV-45779 High Dose v Main Treatment Period: XOLAIR High Dose
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS Mean Difference
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.56
upper limit	0.94

Primary: Relative Potency of TEV-45779 and XOLAIR

End point title	Relative Potency of TEV-45779 and XOLAIR[2]

End point description:

The relative potency of the test drug to the reference drug was defined as the dose of the test drug that produced the same biological response as 1 unit of the dose of the reference drug. The relative potency of TEV-45779 and XOLAIR was measured by change from baseline in ISS7 at Week 12 using a 4-point assay, that is, TEV-45779 High Dose, TEV-45779 Low Dose, XOLAIR High Dose and XOLAIR Low Dose using a multi-step process. Relative potency was demonstrated if the 90% confidence interval (CI) for relative potency fell entirely within the equivalence margins. Relative potency is a unitless measure as it is obtained from a comparison of the dose-response relationship. The ITT analysis set included all

randomized participants. Here, '0.09' and '0.99' signifies 90% CI for the relative potency could not be estimated as the dose-response curve slope p-value was above the limit of 0.05.

End point type	Primary

End point timeframe:

Baseline to Week 12

Notes:

[2] - 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: The reported data is statistical analysis data.

End point values	TEV-45779 vs XOLAIR			
Subject group type	Subject analysis set			
Number of subjects analysed	608			
Units: unitless				
number (confidence interval 90%)	0.89 (0.09 to 0.99)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in the ISS7 at Week 12, TEV-45779 High Dose Compared to XOLAIR High Dose (For Food and Drug Administration [FDA] Submission)

End point title	Change From Baseline in the ISS7 at Week 12, TEV-45779 High Dose Compared to XOLAIR High Dose (For Food and Drug Administration [FDA] Submission)[3]

End point description:

The severity of the itch was recorded by the participants twice daily in their eDiary, on a scale of 0 (none) to 3 (intense/severe). A weekly itch score (ISS7) was defined as the sum of the available daily itch severity scores in that week, divided by the number of days for which a daily itch severity score was available, multiplied by 7. The daily ISS was calculated as the average of the morning and evening scores. The possible range of the weekly score was therefore 0 (best score) to 21 (worst score) with higher scores indicating more severe itching. LS mean and 90% CI were calculated using ANCOVA model. The ITT analysis set included all randomized participants.

End point type	Primary

End point timeframe:

Baseline, Week 12

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The reported data is statistical analysis data.

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: XOLAIR High Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	201	203		
Units: units on a scale				
least squares mean (confidence interval 95%)	-10.77 (-11.61 to -9.93)	-10.38 (-11.24 to -9.52)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Main Treatment Period: TEV-45779 High Dose v Main Treatment Period: XOLAIR High Dose
Number of subjects included in analysis	404
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	LS Mean Difference
Point estimate	-0.39
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.37
upper limit	0.58

Secondary: Change From Baseline in the ISS7 at Weeks 4 and 12

End point title	Change From Baseline in the ISS7 at Weeks 4 and 12

End point description:

The severity of the itch was recorded by the participants twice daily in their eDiary, on a scale of 0 (none) to 3 (intense/severe). A weekly itch score (ISS7) was defined as the sum of the available daily itch severity scores in that week, divided by the number of days for which a daily itch severity score was available, multiplied by 7. The daily ISS was calculated as the average of the morning and evening scores. The possible range of the weekly score was therefore 0 (best score) to 21 (worst score) with higher scores indicating more severe itching. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4 and 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	192	98	198	97
Units: units on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=192,98,198,97)	-7.64 (± 6.383)	-7.35 (± 6.236)	-7.87 (± 6.033)	-7.27 (± 6.084)
Change at Week 12 (n=184,96,196,97)	-10.92 (± 6.512)	-9.96 (± 6.340)	-10.65 (± 6.490)	-10.35 (± 6.082)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Weekly Urticaria Activity Score (UAS7) at Week 12

End point title	Change From Baseline in Weekly Urticaria Activity Score (UAS7) at Week 12

End point description:

The UAS was a composite eDiary-recorded score with numeric severity intensity ratings on a scale of 0 - 3 (0 = none to 3 = intense/severe) for (1) the number of wheals (hives); and (2) the intensity of the itch separately, measured twice daily (morning and evening). The daily UAS was the average of the morning and evening scores, which ranged from 0 (none) to 6 (severe). The UAS7 was the sum of the daily UAS scores over 7 days, which ranged from 0 (minimum) to 42 (highest urticaria severity). Higher scores indicated greater severity of urticaria symptoms. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	96	196	97
Units: units on a scale				
arithmetic mean (standard deviation)	-22.10 (± 13.204)	-20.67 (± 12.223)	-21.73 (± 12.651)	-21.67 (± 12.158)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Complete Responders (UAS7 Score = 0) at Week 12

End point title	Percentage of Complete Responders (UAS7 Score = 0) at Week 12

End point description:

The UAS was a composite eDiary-recorded score with numeric severity intensity ratings on a scale of 0 - 3 (0 = none to 3 = intense/severe) for (1) the number of wheals (hives); and (2) the intensity of the itch separately, measured twice daily (morning and evening). The daily UAS was the average of the morning and evening scores, which ranged from 0 (none) to 6 (severe). The UAS7 was the sum of the daily UAS scores over 7 days, which ranged from 0 (minimum) to 42 (highest urticaria severity). Higher scores indicated greater severity of urticaria symptoms. Complete responders were participants with s

UAS7 score = 0. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	96	196	97
Units: percentage of participants				
number (not applicable)	33.2	28.1	29.6	30.9

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Physician's (In-clinic) Assessment of UAS at Week 12

End point title	Change From Baseline in the Physician's (In-clinic) Assessment of UAS at Week 12

End point description:

Physician’s (in-clinic) assessment of UAS score was performed using the in-clinic UAS. The physician, or the person designated, provided the sum of the score of the participant’s urticaria lesions (number of wheals [hives]) and pruritus (itch) reflective of the participant’s condition over the 12 hours prior to the visit using the rating scale of 0 - 6 (0 = none to 6 = intense/severe). Higher scores indicated greater severity of urticaria symptoms. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	185	96	193	101
Units: units on a scale				
arithmetic mean (standard deviation)	-3.38 (± 2.002)	-3.34 (± 1.907)	-3.55 (± 1.893)	-3.15 (± 2.085)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a UAS7 Score ≤6 at Week 12

End point title	Percentage of Participants With a UAS7 Score ≤6 at Week 12

End point description:

The UAS was a composite eDiary-recorded score with numeric severity intensity ratings on a scale of 0 - 3 (0 = none to 3 = intense/severe) for (1) the number of wheals (hives); and (2) the intensity of the itch separately, measured twice daily (morning and evening). The daily UAS was the average of the morning and evening scores, which ranged from 0 (none) to 6 (severe). The UAS7 is the number of participants achieving the endpoint of less than or equal to 6. UAS7 was calculated as the sum of the daily UAS scores over 7 days, which ranged from 0 (minimum) to 42 (highest urticaria severity). Higher scores indicated greater severity of urticaria symptoms. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	96	196	97
Units: percentage of participants				
number (not applicable)	49.5	45.8	46.4	48.5

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Weekly Number of Wheals Score at Week 12

End point title	Change From Baseline in the Weekly Number of Wheals Score at Week 12

End point description:

The wheals (hives) severity score, defined by number of wheals (hives), was recorded by the participant twice daily in their eDiary, on a scale of 0 (none) to 3 (> 12 hives/12 hours). A weekly number of wheals score was derived by adding up the average daily scores of the 7 days preceding the visit. The possible range of the weekly score was therefore 0 (no wheals) - 21 (highest hives activity). The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	96	196	97
Units: units on a scale				
arithmetic mean (standard deviation)	-11.18 (± 7.127)	-10.70 (± 6.551)	-11.09 (± 6.740)	-11.33 (± 6.672)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Weekly Size of the Largest Wheals Score at Week 12

End point title	Change From Baseline in the Weekly Size of the Largest Wheals Score at Week 12

End point description:

The weekly size of the largest wheals score was calculated from the eDiary data. A wheal score of 0 was assigned when <10 small wheals (diameter <3 centimeters [cm]) were present, presence of 10–50 small wheals or less than 10 large wheals (diameter >3 cm) was denoted by score of 1. A score of 2 was assigned when more than 50 small wheals or 10 to 50 large wheals were present. A score of 3 denoted wheals covering almost the entire body surface area. A weekly score was defined as the sum of the available daily size of the largest wheals scores in that week, divided by the number of days for which a daily score was available, multiplied by 7. The possible range of the weekly score was therefore 0 (best score) to 21 (worst score) with higher scores indicating more severity. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	96	196	97
Units: units on a scale				
arithmetic mean (standard deviation)	-10.28 (± 6.937)	-9.52 (± 6.670)	-10.45 (± 6.745)	-10.68 (± 6.838)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Angioedema-Free Days from Week 4 to Week 12

End point title	Percentage of Angioedema-Free Days from Week 4 to Week 12

End point description:

Percentage of angioedema-free days from Week 4 to Week 12 were calculated based on the diary data as the number of days in the diary between the dates of Week 4 and Week 12 visits with no angioedema episodes, divided by the total number of days with diary entries in this time span * 100%. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 4 to Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	195	99	202	102
Units: percentage of days				
median (full range (min-max))	100.00 (0.0 to 100.0)	100.00 (0.0 to 100.0)	100.00 (0.0 to 100.0)	100.00 (0.0 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of ISS7 MID Responders at Week 12

End point title	Percentage of ISS7 MID Responders at Week 12

End point description:

A responder was defined as a participant with a reduction from baseline in ISS7 of ≥5 points in ISS7 score. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	96	196	97
Units: percentage of participants				
number (not applicable)	81.0	78.1	80.6	79.4

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Minimally Important Difference (MID) Response in ISS7 Score

End point title	Time to Minimally Important Difference (MID) Response in ISS7 Score

End point description:

Time to MID response was defined as time to a reduction from baseline in ISS7 of ≥5 points in ISS7 score by Week 12. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants achieving MID up to Week 12. Here, 0.99 and 9.99 represents data not estimable (NE) because basic assumptions were not met.

End point type	Secondary

End point timeframe:

Baseline up to Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	177	87	185	87
Units: weeks				
median (confidence interval 95%)	2.0 (2.0 to 3.0)	2.0 (1.0 to 2.0)	2.0 (0.99 to 9.99)	2.0 (2.0 to 3.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Overall Dermatology Life Quality Index (DLQI) Score at Week 12

End point title	Change From Baseline in the Overall Dermatology Life Quality Index (DLQI) Score at Week 12

End point description:

The DLQI consisted of 10 questions concerning participants' perception of the impact of skin diseases on different aspects of their health-related quality of life over the last week. The DLQI total score was calculated by adding the score of each question (scored as follows: Very much = 3; Yes [in question 7.a] = 3; A lot = 2; A little = 1; Not at all = 0; Not relevant = 0; No [in question 7.a] = 0; Question unanswered = 0), resulting in a maximum of 30 and a minimum of 0. The higher the score, the more the quality of life was impaired. A score higher than 10 indicated that the participant's life was being severely affected by their skin disease. The ITT analysis set included all randomized participants. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	188	98	193	100
Units: units on a scale				
arithmetic mean (standard deviation)	-9.72 (± 7.125)	-8.40 (± 7.28)	-9.54 (± 7.091)	-8.09 (± 6.432)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Week 12 in ISS7 at Weeks 24 and 40

End point title	Change From Week 12 in ISS7 at Weeks 24 and 40

End point description:

The severity of the itch was recorded by the participants twice daily in their eDiary, on a scale of 0 (none) to 3 (intense/severe). A weekly itch score (ISS7) was defined as the sum of the available daily itch severity scores in that week, divided by the number of days for which a daily itch severity score was available, multiplied by 7. The daily ISS was calculated as the average of the morning and evening scores. The possible range of the weekly score was therefore 0 (best score) to 21 (worst score) with higher scores indicating more severe itching. The transition intent-to-treat (TITT) analysis set included all participants re-randomized in the transition period. 'Overall number of participants analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Week 12, Weeks 24 and 40

End point values	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	91	91	46
Units: units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=170,91,91,46,93,47)	-1.64 (± 3.598)	-1.37 (± 4.576)	-1.82 (± 4.016)	-1.21 (± 3.186)
Change at Week 40 (n=145,75,75,39,83,39)	1.84 (± 7.182)	0.44 (± 6.982)	1.43 (± 6.870)	1.58 (± 5.274)

End point values	Transition Period: XOLAIR/TEV-45779 High Dose	Transition Period: XOLAIR/TEV-45779 Low Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	47		
Units: units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=170,91,91,46,93,47) Change at Week 40 (n=145,75,75,39,83,39)	-1.78 (± 4.226) 2.03 (± 7.969)	-2.09 (± 4.585) 1.27 (± 6.718)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Week 12 in the UAS7 at Week 24

End point title	Change From Week 12 in the UAS7 at Week 24

End point description:

The UAS was a composite eDiary-recorded score with numeric severity intensity ratings on a scale of 0 - 3 (0 = none to 3 = intense/severe) for (1) the number of wheals (hives); and (2) the intensity of the itch separately, measured twice daily (morning and evening). The daily UAS was the average of the morning and evening scores, which can range from 0 (none) to 6 (severe). The UAS7 was the sum of the daily UAS scores over 7 days, which can range from 0 (minimum) to 42 (highest urticaria severity). Higher scores indicated greater severity of urticaria symptoms. The TITT analysis set included all participants re-randomized in the transition period. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 12, Week 24

End point values	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	91	91	46
Units: units on a scale				
arithmetic mean (standard deviation)	-3.37 (± 6.641)	-2.66 (± 9.524)	-3.65 (± 7.953)	-2.54 (± 7.546)

End point values	Transition Period:	Transition Period:		

	XOLAIR/TEV-45779 High Dose	XOLAIR/TEV-45779 Low Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	47		
Units: units on a scale				
arithmetic mean (standard deviation)	-3.45 (± 8.387)	-3.12 (± 9.419)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Week 12 in the Weekly Number of Wheals Score at Weeks 24 and 40

End point title	Change From Week 12 in the Weekly Number of Wheals Score at Weeks 24 and 40

End point description:

The wheals (hives) severity score, defined by number of wheals (hives), was recorded by the participant twice daily in their eDiary, on a scale of 0 (none) to 3 (> 12 hives/12 hours). A weekly number of wheals score was derived by adding up the average daily scores of the 7 days preceding the visit. The possible range of the weekly score was therefore 0 (no wheals) - 21 (highest hives activity). The TITT analysis set included all participants re-randomized in the transition period. 'Overall number of participants analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Week 12, Weeks 24 and 40

End point values	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	91	91	46
Units: units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=170,91,91,46,93,47)	-1.73 (± 3.649)	-1.29 (± 5.262)	-1.84 (± 4.139)	-1.33 (± 4.793)
Change at Week 40 (n=145,75,75,39,83,39)	1.87 (± 7.412)	0.60 (± 8.236)	1.53 (± 6.953)	2.05 (± 6.110)

End point values	Transition Period: XOLAIR/TEV-45779 High Dose	Transition Period: XOLAIR/TEV-45779 Low Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	47		

Units: units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=170,91,91,46,93,47) Change at Week 40 (n=145,75,75,39,83,39)	-1.67 (± 4.510) 2.77 (± 8.620)	-1.03 (± 5.281) 2.13 (± 7.809)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Week 12 in the Physician's (In-clinic) Assessment of UAS7 at Week 24

End point title	Change From Week 12 in the Physician's (In-clinic) Assessment of UAS7 at Week 24

End point description:

Physician’s (in-clinic) assessment of UAS score was performed using the in-clinic UAS. The physician, or the person designated, provided the sum of the score of the participant’s urticaria lesions (number of wheals [hives]) and pruritus (itch) reflective of the participant’s condition over the 12 hours prior to the visit using the rating scale of 0 - 6 (0 = none to 6 = intense/severe). Higher scores indicated greater severity of urticaria symptoms. The TITT analysis set included all participants re-randomized in the transition period. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 12, Week 24

End point values	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	175	91	93	49
Units: units on a scale				
arithmetic mean (standard deviation)	-0.55 (± 1.556)	-0.40 (± 2.032)	-0.27 (± 1.360)	-0.53 (± 1.838)

End point values	Transition Period: XOLAIR/TEV-45779 High Dose	Transition Period: XOLAIR/TEV-45779 Low Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	92	48		
Units: units on a scale				
arithmetic mean (standard deviation)	-0.38 (± 1.413)	-0.67 (± 1.548)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Week 12 in the Weekly Size of the Largest Wheals Score at Weeks 24 and 40

End point title	Change From Week 12 in the Weekly Size of the Largest Wheals Score at Weeks 24 and 40

End point description:

The weekly size of the largest wheals score was calculated from eDiary data. A wheal score of 0 was assigned when <10 small wheals (diameter <3 cm) were present, presence of 10–50 small wheals or less than 10 large wheals (diameter >3 cm) was denoted by score 1. A score of 2 was assigned when more than 50 small wheals or 10 to 50 large wheals were present. A score of 3 denoted wheals covering almost the entire body surface area. A weekly score was defined as sum of available daily size of the largest wheals scores in that week, divided by the number of days for which a daily score was available, multiplied by 7. The possible range of the weekly score was therefore 0 (best score) to 21 (worst score) with higher scores indicating more severity. The TITT analysis set included all participants re-randomized in the transition period. 'Overall number of participants analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Week 12, Weeks 24 and 40

End point values	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	91	91	46
Units: units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=170,91,91,46,93,47)	-1.87 (± 3.898)	-1.28 (± 4.697)	-1.78 (± 4.334)	-1.18 (± 4.464)
Change at Week 40 (n=145,75,75,39,83,39)	1.46 (± 7.434)	0.72 (± 7.899)	1.34 (± 7.332)	2.35 (± 5.968)

End point values	Transition Period: XOLAIR/TEV-45779 High Dose	Transition Period: XOLAIR/TEV-45779 Low Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	93	47		
Units: units on a scale				
arithmetic mean (standard deviation)				

Change at Week 24 (n=170,91,91,46,93,47) Change at Week 40 (n=145,75,75,39,83,39)	-1.94 (± 4.776) 2.71 (± 8.706)	-0.88 (± 4.456) 1.87 (± 7.798)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Angioedema-Free Days from Week 12 to Week 24

End point title	Percentage of Angioedema-Free Days from Week 12 to Week 24

End point description:

Percentage of angioedema-free days from Week 12 to Week 24 was calculated based on the diary data as the number of days in the diary between the dates of Week 12 and Week 24 visits with no angioedema episodes, divided by the total number of days with diary entries in this time span * 100%. The TITT analysis set included all participants re-randomized in the transition period. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Week 12 to Week 24

End point values	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	97	97	51
Units: percentage of days				
median (full range (min-max))	100.00 (0.0 to 100.0)	100.00 (0.0 to 100.0)	100.00 (0.0 to 100.0)	100.00 (0.0 to 100.0)

End point values	Transition Period: XOLAIR/TEV-45779 High Dose	Transition Period: XOLAIR/TEV-45779 Low Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	50		
Units: percentage of days				
median (full range (min-max))	100.00 (0.0 to 100.0)	100.00 (0.0 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Week 12 in the Overall DLQI Score at Weeks 24 and 40

End point title	Change From Week 12 in the Overall DLQI Score at Weeks 24 and 40

End point description:

The DLQI consisted of 10 questions concerning participants' perception of the impact of skin diseases on different aspects of their health-related quality of life over the last week. The DLQI total score was calculated by adding the score of each question (scored as follows: Very much = 3; Yes [in question 7.a] = 3; A lot = 2; A little = 1; Not at all = 0; Not relevant = 0; No [in question 7.a] = 0; Question unanswered = 0), resulting in a maximum of 30 and a minimum of 0. The higher the score, the more the quality of life was impaired. A score higher than 10 indicated that the participant's life was being severely affected by their skin disease. The TITT analysis set included all participants re-randomized in the transition period. 'Overall number of participants analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable at specified timepoint.

End point type	Secondary

End point timeframe:

Week 12, Weeks 24 and 40

End point values	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	179	93	93	49
Units: units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=179,93,93,49,94,48)	-1.44 (± 3.621)	-0.43 (± 5.619)	-1.19 (± 4.387)	-1.82 (± 5.552)
Change at Week 40 (n=160,83,85,41,86,42)	1.65 (± 7.581)	1.05 (± 7.545)	0.51 (± 7.096)	0.39 (± 5.098)

End point values	Transition Period: XOLAIR/TEV-45779 High Dose	Transition Period: XOLAIR/TEV-45779 Low Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	48		
Units: units on a scale				
arithmetic mean (standard deviation)				
Change at Week 24 (n=179,93,93,49,94,48)	-0.88 (± 4.788)	-1.60 (± 4.271)		
Change at Week 40 (n=160,83,85,41,86,42)	2.45 (± 7.791)	1.10 (± 7.570)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With at Least One Treatment-emergent Adverse Event (TEAE) in the Main Treatment Period

End point title	Number of Participants With at Least One Treatment-emergent Adverse Event (TEAE) in the Main Treatment Period

End point description:

An adverse event (AE) was defined as any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. Serious AEs (SAEs) were defined as death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect, or an important medical event that jeopardized participant and required medical intervention to prevent 1 of the outcomes listed in this definition. AEs were considered TEAEs if onset occurred or worsened on or after the first dose date. A summary of other non-serious AEs and all serious AEs, regardless of causality is located in Reported AE section. The main treatment period safety analysis set included all randomized participants who received at least 1 dose of study drug during the main treatment period.

End point type	Secondary

End point timeframe:

Baseline up to Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	201	102	203	102
Units: participants	64	37	71	33

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With at Least One TEAE Week 12 up to Week 24

End point title	Number of Participants With at Least One TEAE Week 12 up to Week 24

End point description:

An AE was defined as any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. SAEs were defined as death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect, or an important medical event that jeopardized participant and required medical intervention to prevent 1 of the outcomes listed in this definition. AEs were considered TEAEs if onset occurred or worsened on or after the first dose date. A summary of other non-serious AEs and all serious AEs, regardless of causality is located in Reported AE section. The transition period safety analysis set included all randomized participants who received the study drug at Week 12.

End point type	Secondary

End point timeframe:

Week 12 up to Week 24

End point values	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	188	98	97	51
Units: participants	78	34	43	18

End point values	Transition Period: XOLAIR/TEV-45779 High Dose	Transition Period: XOLAIR/TEV-45779 Low Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	50		
Units: participants	38	16		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Antidrug Antibodies (ADAs) in the Main Treatment Period

End point title	Number of Participants With Antidrug Antibodies (ADAs) in the Main Treatment Period

End point description:

Number of participants with positive ADA treatment-related, positive ADA not treatment-related, and negative ADA are reported. The main treatment period safety analysis set included all randomized participants who received at least 1 dose of study drug during the main treatment period. 'Overall number of participants analyzed' = participants with ADA status at any time during the main treatment period.

End point type	Secondary

End point timeframe:

Baseline up to Week 12

End point values	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Main Treatment Period: XOLAIR High Dose	Main Treatment Period: XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	101	201	102
Units: participants				
Positive, Treatment Related	18	6	37	13
Positive, Not Treatment Related	8	5	5	4
Negative	173	90	159	85

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With ADAs in the Transition Period from Week 12 to Week 24

End point title	Number of Participants With ADAs in the Transition Period from Week 12 to Week 24

End point description:

Number of participants with positive ADA treatment-related, positive ADA not treatment-related, and negative ADA are reported. The transition period safety analysis set included all randomized participants who received the study drug at Week 12. 'Overall number of participants analyzed' = participants with ADA status at any time during the transition period.

End point type	Secondary

End point timeframe:

Week 12 up to Week 24

End point values	Transition Period: TEV-45779/TEV-45779 High Dose	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	182	95	96	50
Units: participants				
Positive, Treatment Related	34	15	10	4
Positive, Not Treatment Related	6	4	3	1
Negative	142	76	83	45

End point values	Transition Period: XOLAIR/TEV-45779 High Dose	Transition Period: XOLAIR/TEV-45779 Low Dose		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	96	48		
Units: participants				
Positive, Treatment Related	14	8		
Positive, Not Treatment Related	1	2		
Negative	81	38		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to Week 40

Adverse event reporting additional description:

The safety analysis set included all randomized participants who received at least 1 dose of study drug. The transition period safety analysis set included all randomized participants who received the study drug at Week 12.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Main Treatment Period: TEV-45779 High Dose

Reporting group description:

Participants received TEV-45779 SC injection at a high dose level Q4W at Weeks 0, 4, and 8.

Reporting group title	Main Treatment Period: TEV-45779 Low Dose

Reporting group description:

Participants received TEV-45779 SC injection at a low dose level Q4W at Weeks 0, 4, and 8.

Reporting group title	Transition Period: XOLAIR/TEV-45779 Low Dose

Reporting group description:

Participants who received XOLAIR SC injection at a low dose level in the main treatment period, received TEV-45779 at a low dose level at Weeks 12, 16, and 20 in the transition period.

Reporting group title	Transition Period: TEV-45779/TEV-45779 Low Dose

Reporting group description:

Participants who received TEV-45779 SC injection at a low dose level in the main treatment period continued to receive TEV-45779 at the same dose level at Weeks 12, 16, and 20 in the transition period.

Reporting group title	Transition Period: XOLAIR/XOLAIR High Dose

Reporting group description:

Participants who received XOLAIR SC injection at a high dose level in the main treatment period continued to receive XOLAIR at the same dose level at Weeks 12, 16, and 20 in the transition period.

Reporting group title	Transition Period: XOLAIR/XOLAIR Low Dose

Reporting group description:

Participants who received XOLAIR SC injection at a low dose level in the main treatment period continued to receive XOLAIR at the same dose level at Weeks 12, 16, and 20 in the transition period.

Reporting group title	Transition Period: XOLAIR/TEV-45779 High Dose

Reporting group description:

Participants who received XOLAIR SC injection at a high dose level in the main treatment period, received TEV-45779 at a high dose level at Weeks 12, 16, and 20 in the transition period.

Reporting group title	Main Treatment Period: XOLAIR Low Dose

Reporting group description:

Participants received XOLAIR SC injection at a low dose level Q4W at Weeks 0, 4, and 8.

Reporting group title	Main Treatment Period: XOLAIR High Dose

Reporting group description:

Participants received XOLAIR SC injection at a high dose level Q4W at Weeks 0, 4, and 8.

Reporting group title	Transition Period: TEV-45779/TEV-45779 High Dose

Reporting group description:

Participants who received TEV-45779 SC injection at a high dose level in the main treatment period continued to receive TEV-45779 at the same dose level at Weeks 12, 16, and 20 in the transition period.

Serious adverse events	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Transition Period: XOLAIR/TEV-45779 Low Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 201 (0.50%)	0 / 102 (0.00%)	1 / 50 (2.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Lower limb fracture			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strangulated umbilical hernia			
subjects affected / exposed	1 / 201 (0.50%)	0 / 102 (0.00%)	0 / 50 (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
Pancreatitis			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Adenomyosis			

subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Erysipelas			

subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottitis			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis chronic			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 201 (0.00%)	0 / 102 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 98 (3.06%)	4 / 97 (4.12%)	0 / 51 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Lower limb fracture			
subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			

subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strangulated umbilical hernia			
subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 98 (0.00%)	1 / 97 (1.03%)	0 / 51 (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
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	1 / 98 (1.02%)	1 / 97 (1.03%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	1 / 98 (1.02%)	0 / 97 (0.00%)	0 / 51 (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
Chondromalacia			
subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Erysipelas			
subjects affected / exposed	0 / 98 (0.00%)	0 / 97 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottitis			
subjects affected / exposed	0 / 98 (0.00%)	1 / 97 (1.03%)	0 / 51 (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
Pyelonephritis chronic			
subjects affected / exposed	0 / 98 (0.00%)	1 / 97 (1.03%)	0 / 51 (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
Urinary tract infection			
subjects affected / exposed	1 / 98 (1.02%)	0 / 97 (0.00%)	0 / 51 (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

Serious adverse events	Transition Period: XOLAIR/TEV-45779 High Dose	Main Treatment Period: XOLAIR Low Dose	Main Treatment Period: XOLAIR High Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 97 (1.03%)	0 / 102 (0.00%)	3 / 203 (1.48%)
number of deaths (all causes)	0	0	0
number of deaths resulting from			

adverse events			
Injury, poisoning and procedural complications			
Lower limb fracture			
subjects affected / exposed	1 / 97 (1.03%)	0 / 102 (0.00%)	0 / 203 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strangulated umbilical hernia			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Erysipelas			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottitis			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis chronic			

subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 97 (0.00%)	0 / 102 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Transition Period: TEV-45779/TEV-45779 High Dose		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 188 (2.13%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Lower limb fracture			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Strangulated umbilical hernia			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			

subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	1 / 188 (0.53%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 188 (0.53%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	1 / 188 (0.53%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chondromalacia			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome			

subjects affected / exposed	1 / 188 (0.53%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Erysipelas			
subjects affected / exposed	1 / 188 (0.53%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epiglottitis			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis chronic			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 188 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Main Treatment Period: TEV-45779 High Dose	Main Treatment Period: TEV-45779 Low Dose	Transition Period: XOLAIR/TEV-45779 Low Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 201 (14.93%)	19 / 102 (18.63%)	6 / 50 (12.00%)
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	15 / 201 (7.46%)	10 / 102 (9.80%)	3 / 50 (6.00%)
occurrences (all)	24	14	8
Injection site induration			
subjects affected / exposed	12 / 201 (5.97%)	6 / 102 (5.88%)	3 / 50 (6.00%)
occurrences (all)	17	6	9
Injection site pain			

subjects affected / exposed	13 / 201 (6.47%)	9 / 102 (8.82%)	2 / 50 (4.00%)
occurrences (all)	30	11	6
Injection site swelling			
subjects affected / exposed	9 / 201 (4.48%)	4 / 102 (3.92%)	3 / 50 (6.00%)
occurrences (all)	10	4	8
Infections and infestations			
COVID-19			
subjects affected / exposed	5 / 201 (2.49%)	5 / 102 (4.90%)	2 / 50 (4.00%)
occurrences (all)	5	5	2
Upper respiratory tract infection			
subjects affected / exposed	5 / 201 (2.49%)	3 / 102 (2.94%)	1 / 50 (2.00%)
occurrences (all)	5	4	1

Non-serious adverse events	Transition Period: TEV-45779/TEV-45779 Low Dose	Transition Period: XOLAIR/XOLAIR High Dose	Transition Period: XOLAIR/XOLAIR Low Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 98 (11.22%)	16 / 97 (16.49%)	8 / 51 (15.69%)
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	5 / 98 (5.10%)	3 / 97 (3.09%)	2 / 51 (3.92%)
occurrences (all)	6	4	3
Injection site induration			
subjects affected / exposed	3 / 98 (3.06%)	3 / 97 (3.09%)	1 / 51 (1.96%)
occurrences (all)	4	4	1
Injection site pain			
subjects affected / exposed	3 / 98 (3.06%)	2 / 97 (2.06%)	2 / 51 (3.92%)
occurrences (all)	7	2	4
Injection site swelling			
subjects affected / exposed	1 / 98 (1.02%)	3 / 97 (3.09%)	0 / 51 (0.00%)
occurrences (all)	1	3	0
Infections and infestations			
COVID-19			
subjects affected / exposed	5 / 98 (5.10%)	7 / 97 (7.22%)	3 / 51 (5.88%)
occurrences (all)	5	7	3
Upper respiratory tract infection			
subjects affected / exposed	1 / 98 (1.02%)	5 / 97 (5.15%)	2 / 51 (3.92%)
occurrences (all)	1	5	2

Non-serious adverse events	Transition Period: XOLAIR/TEV-45779 High Dose	Main Treatment Period: XOLAIR Low Dose	Main Treatment Period: XOLAIR High Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 97 (10.31%)	10 / 102 (9.80%)	30 / 203 (14.78%)
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	6 / 97 (6.19%)	7 / 102 (6.86%)	13 / 203 (6.40%)
occurrences (all)	9	12	21
Injection site induration			
subjects affected / exposed	3 / 97 (3.09%)	5 / 102 (4.90%)	12 / 203 (5.91%)
occurrences (all)	5	7	15
Injection site pain			
subjects affected / exposed	1 / 97 (1.03%)	5 / 102 (4.90%)	11 / 203 (5.42%)
occurrences (all)	2	11	21
Injection site swelling			
subjects affected / exposed	0 / 97 (0.00%)	3 / 102 (2.94%)	4 / 203 (1.97%)
occurrences (all)	0	4	4
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 97 (1.03%)	0 / 102 (0.00%)	8 / 203 (3.94%)
occurrences (all)	1	0	8
Upper respiratory tract infection			
subjects affected / exposed	1 / 97 (1.03%)	0 / 102 (0.00%)	2 / 203 (0.99%)
occurrences (all)	1	0	2

Non-serious adverse events	Transition Period: TEV-45779/TEV-45779 High Dose		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 188 (15.43%)		
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	8 / 188 (4.26%)		
occurrences (all)	17		
Injection site induration			
subjects affected / exposed	7 / 188 (3.72%)		
occurrences (all)	15		
Injection site pain			

subjects affected / exposed occurrences (all) Injection site swelling subjects affected / exposed occurrences (all)	8 / 188 (4.26%) 14 6 / 188 (3.19%) 9		
Infections and infestations COVID-19 subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	 9 / 188 (4.79%) 9 9 / 188 (4.79%) 11		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 June 2021	The following major procedural changes (not all-inclusive) were made to the protocol: - Added information on blinded interim safety analysis to provide the most recent information available. - Added DLQI as an additional secondary efficacy parameter for the main and transition period and included description of DLQI. - Added justification for equivalence margins chosen for the primary efficacy analysis. - Added clarification for the use of single H1 antihistamine at stable and fixed doses not exceeding label recommendations as the standard treatment regimen for participants throughout the trial. - Added timepoints for DLQI completion and additional timepoint for weight measurement. - Revised to reflect omission of unblinded analysis of the main treatment period after Week 12. - Revised to include Common Terminology Criteria for Adverse Events (CTCAE) scale for grading of AEs. - Revised to capture all injection site findings as AEs. - Added region (America, Europe and Asia-Pacific) as a covariate for primary and co-primary analysis for European Medicines Agency (EMA) and Food and Drug Administration (FDA) submissions, respectively.
23 November 2021	The following major procedural changes (not all-inclusive) were made to the protocol: - Generalized the need to maintain the treatment blind not limited to the participants. Correction of reference visit for the dosing level. - Removal of stopping criteria like death, life-threatening SAE, grade 3 or higher AEs and clinically significant grade 3 or higher laboratory abnormality assessed to be related to the investigational medicinal product (IMP) by the investigator from the protocol. - Specified the minimal interval of at least 5 days between Visit 1 and Visit 2 and also clarified the 3-day adjustment period for participants to reach an approved dose of their H1 antihistamine treatment needing an interval of at least 8 days; aligned IMP injection sites with the pharmacy manual and updated to new eDiary compliance requirements. - Changed eDiary compliance to allow missing data as part of the inclusion criteria instead of the original full 7 days. - Modified the withdrawal criteria due to use of concomitant medications - allowing participants to continue the trial under certain circumstances. - Included instructions for allowing one re-screening of a participant who previously screen failed and the process for obtaining this approval. - Corrected how the blinding and randomization was performed and differentiated between sponsor and non-sponsor blinding. - Clarified the IMP injection site. Reinstated the analysis of the main treatment period based on newly available FDA input and removed redundant section. - Described new interval requirements between Visit 1 and Visit 2 and 3-day adjustment to normal dose which was part of the screening process. Addition of a 2-day window to allow Visit 2 scheduling flexibility. - Prohibited medications list was updated based on current clinical understanding.
10 May 2022	The following major procedural changes (not all-inclusive) were made to the protocol: - Total duration of the trial was changed to 43 weeks by addition of up to 3 weeks of screening period, 24 weeks of trial treatment and 16 weeks of follow-up. - Addition of text related to reporting of medical history for clarity. - Aligned text related to use of H1 antihistamines in exclusion criterion with inclusion criterion. - Added a statement forbidding donation of blood for the duration of the trial. - Protocol was updated with requirements for reporting medical history to align with exclusion criteria. - Clarified that coronavirus disease 2019 (COVID-19) testing at screening (Visit 1) was mandatory and that testing would only be performed locally. - Clarified that injection site findings did not need to be captured generally as AEs.

15 February 2023	The following major procedural changes (not all-inclusive) were made to the protocol: - Clarified that relative potency of TEV-45779 and XOLAIR was measured by change from baseline in ISS7 at Week 12. - Deleted the term 'United States (US)-licensed' as both XOLAIR sourced from the European Union (EU) and US could be used as reference product. - Updated trial timeline according to the latest information. - Corrected table information to clarify that rescue medication was dispensed at Visit 1 and Visits 2-12. - Added method of calculating the next visit for cases of out-of-window visits. - Clarification on dispensing of rescue medication. - Added footnote for clarification on diagnosis criteria. - Clarified that inclusion criteria was revised (that is, 'with spermicide' deleted) during Protocol Amendment 3. - Clarified usage and distribution of eDiary. - Updated exclusion criteria to aid with enrolment - Updated Withdrawal Criteria and Procedures for the participants who discontinued from IMP. - Added clarification on unblinded staff. - Updated the section to provide clarification on blinding and unblinding of staff. - Clarification on reporting of participant pregnancies. - Clarified that laboratory test results at initial screening visit were recorded under medical history.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported