Clinical trial results:
Clinical Trial Exit Interview Study in Cutaneous T-cell Lymphoma (CTCL) to Capture Meaningful Treatment Benefit from a Patient's Perspective

Summary

EudraCT number	2020-001992-34
Trial protocol	DE
Global end of trial date	16 April 2021

Results information

Result version number	v1 (current)
This version publication date	01 November 2022
First version publication date	01 November 2022

Trial information

Trial identification

Sponsor protocol code	EVM-22656

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Galderma R&D SNC
Sponsor organisation address	Les Templiers, 2400 route des Colles, Biot, France, 06410
Public contact	CTA Coordinator, Galderma R&D SNC, +33 493-95-70-85, cta.coordinator@galderma.com
Scientific contact	CTA Coordinator, Galderma R&D SNC, +33 493-95-70-85, cta.coordinator@galderma.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	31 August 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 April 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to characterize subjects experienced treatment benefit of CD11301 gel:
a. Provide a subject-focused assessment of disease burden.
b. Capture subjects experience of the study treatment (what are the perceived benefits and risks of treatment, changes in subjects daily life since baseline, unexpected treatment effects, subjects treatment expectations, satisfaction and comparison to previous treatments).
c. Explore subjects perceptions of meaningful change from baseline (i.e., what constitutes a meaningful treatment effect, which aspects are most relevant and most meaningful to subjects).

Protection of trial subjects:

This study was performed in compliance with Good Clinical Practice (GCP) including the archiving of essential study documents. All data provided either to the Investigator (and study staff) or collected during the study and/or reported herein should be regarded as confidential and proprietary in nature and should not be disclosed to any third party without the written consent of Galderma.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 April 2019
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	Germany: 5
Country: Number of subjects enrolled	United States: 14
Worldwide total number of subjects	19
EEA total number of subjects	5

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)	14
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 3 clinical sites (one in Germany and two in United States) from 30 April 2019 to 16 April 2021.

Pre-assignment

Screening details:

A total of 19 subjects who met predefined inclusion/exclusion criteria, expressed an interest in participating in the interview study, and provided consent were enrolled.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Single blind
Roles blinded	Investigator[1]

Blinding implementation details:

Interviewers i.e., clinicians who met eligibility criteria were blinded to the treatment assignment.

Arms

Are arms mutually exclusive?	Yes
Arm title	CTCL Stage IA

Arm description:

Subjects who had early stage disease (CTCL stage IA) were treated with placebo and resiquimod gel (0.03 percent (%) or 0.06%) for eight weeks during cycle 1 followed by resiquimod gel (0.03% or 0.06%) for eight weeks during cycle 2. Subjects who treated with placebo in cycle 1 received resiquimod gel 0.03% during Cycle 2. The two treatment cycles were having duration of 12 weeks of each (eight weeks of treatment plus four weeks of treatment-free) were followed by a 12 weeks treatment-free follow-up period. Those eligible trial subjects were interviewed after completion of either of the treatment cycle for 3 weeks.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical

Dosage and administration details:

Subjects were applied placebo gel topically in cycle 1.

Investigational medicinal product name	Resiquimod gel (CD11301 gel) 0.03 percent (%) or 0.06%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical

Dosage and administration details:

Subjects were treated with resiquimod gel (CD11301 gel) 0.03 percent (%) or 0.06% topically between 2 treatment cycles.

Arm title	CTCL Stage IB

Arm description:

Subjects who had early CTCL stage disease (CTCL stage IB) were treated with placebo and resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 1 followed by resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 2. Subjects who treated with placebo in Cycle 1 received resiquimod gel 0.03% during Cycle 2. The two treatment cycles were having duration of 12 weeks of each (eight weeks of treatment plus four weeks of treatment-free) were followed by a 12 week treatment-free follow-up

period. Those eligible trial participants were interviewed after completion of either of the treatment cycle for 3 weeks.

Arm type	Experimental
Investigational medicinal product name	Resiquimod (0.03% or 0.06% gel)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical

Dosage and administration details:

Subjects were treated topically with resiquimod gel (CD11301 gel) 0.03 percent (%) or 0.06% topically between 2 treatment cycles.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical

Dosage and administration details:

Subjects were treated with placebo gel topically in cycle 1.

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Eligible Interviewers i.e., clinical investigators who conducted interviews of the subjects were blinded to the treatment assignment.

Number of subjects in period 1	CTCL Stage IA	CTCL Stage IB
Started	11	8
Completed	10	7
Not completed	1	1
Early discontinuer	1	1

Baseline characteristics

Reporting groups	
Reporting group title	CTCL Stage IA

Reporting group description:

Subjects who had early stage disease (CTCL stage IA) were treated with placebo and resiquimod gel (0.03 percent (%) or 0.06%) for eight weeks during cycle 1 followed by resiquimod gel (0.03% or 0.06%) for eight weeks during cycle 2. Subjects who treated with placebo in cycle 1 received resiquimod gel 0.03% during Cycle 2. The two treatment cycles were having duration of 12 weeks of each (eight weeks of treatment plus four weeks of treatment-free) were followed by a 12 weeks treatment-free follow-up period. Those eligible trial subjects were interviewed after completion of either of the treatment cycle for 3 weeks.

Reporting group title	CTCL Stage IB

Reporting group description:

Subjects who had early CTCL stage disease (CTCL stage IB) were treated with placebo and resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 1 followed by resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 2. Subjects who treated with placebo in Cycle 1 received resiquimod gel 0.03% during Cycle 2. The two treatment cycles were having duration of 12 weeks of each (eight weeks of treatment plus four weeks of treatment-free) were followed by a 12 week treatment-free follow-up period. Those eligible trial participants were interviewed after completion of either of the treatment cycle for 3 weeks.

Reporting group values	CTCL Stage IA	CTCL Stage IB	Total
Number of subjects	11	8	19
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	52.4	55.1	
standard deviation	± 12	± 18.1	-
Gender categorical Units: Subjects			
Female	0	3	3
Male	11	5	16
Race Units: Subjects			
White	9	6	15
Black	0	2	2
Asian	1	0	1
Other	1	0	1
Ethnicity Units: Subjects			
Not Hispanic or Latino	9	8	17
Hispanic or Latino	2	0	2
CountryUS Units: Subjects			
US	9	5	14
Germany	2	3	5

End points

End points reporting groups

Reporting group title	CTCL Stage IA

Reporting group description:

Subjects who had early stage disease (CTCL stage IA) were treated with placebo and resiquimod gel (0.03 percent (%) or 0.06%) for eight weeks during cycle 1 followed by resiquimod gel (0.03% or 0.06%) for eight weeks during cycle 2. Subjects who treated with placebo in cycle 1 received resiquimod gel 0.03% during Cycle 2. The two treatment cycles were having duration of 12 weeks of each (eight weeks of treatment plus four weeks of treatment-free) were followed by a 12 weeks treatment-free follow-up period. Those eligible trial subjects were interviewed after completion of either of the treatment cycle for 3 weeks.

Reporting group title	CTCL Stage IB

Reporting group description:

Subjects who had early CTCL stage disease (CTCL stage IB) were treated with placebo and resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 1 followed by resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 2. Subjects who treated with placebo in Cycle 1 received resiquimod gel 0.03% during Cycle 2. The two treatment cycles were having duration of 12 weeks of each (eight weeks of treatment plus four weeks of treatment-free) were followed by a 12 week treatment-free follow-up period. Those eligible trial participants were interviewed after completion of either of the treatment cycle for 3 weeks.

Subject analysis set title	Total Number Of Subjects in Exit Interview Sample Study
Subject analysis set type	Full analysis

Subject analysis set description:

Total Number Of Subjects in Exit Interview Sample Study

Primary: Number of Subjects Who Described Their CTCL Diagnosis Experience of Early CTCL Stage

End point title	Number of Subjects Who Described Their CTCL Diagnosis Experience of Early CTCL Stage[1]

End point description:

The subject interview guide was used to explore their CTCL diagnosis experience (burned or itchy lesions, enquired doctor about their skin condition, misdiagnosed or treated for other diseases) of early CTCL stage. Subjects who described their CTCL diagnosis experience of early CTCL stage before entering in the qualitative interview study were reported in this endpoint.

End point type	Primary

End point timeframe:

At Baseline

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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects				
Burned or Itchy Lesions	5			
Enquired Doctor About Their Skin Condition	4			
Misdiagnosed or treated for other diseases	15			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Reported Treatment Experience Prior to Clinical Trial

End point title	Number of Subjects Who Reported Treatment Experience Prior to Clinical Trial[2]

End point description:

The subjects who reported treatment experience prior to clinical trial were evaluated with the use of subject interview guide. Subjects who received treatments (corticosteroids, chemotherapy, retinoid, over-the-counter medication, moisturizers/cream/shampoo, light therapy, oral medication, radiation, other investigational treatments, injection, holistic, antibiotic) before entering in the qualitative interview study were reported for this endpoint.

End point type	Primary

End point timeframe:

At Baseline

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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: subjects				
Corticosteroids	12			
Chemotherapy	4			
Retinoid	2			
Over-the-counter Moisturizers/Cream/Shampoo	4			
Light Therapy	10			
Oral Medication	5			
Radiation	4			
Other Investigational Treatments	2			
Injection	1			
Holistic	1			
Antibiotic	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Experienced Symptoms of Early CTCL Stage

End point title	Number of Subjects Experienced Symptoms of Early CTCL Stage[3]

End point description:

The subjects experience of early CTCL stage symptoms were evaluated with the use of subject interview guide. The number of subjects who described the CTCL-related symptoms (redness, dryness, itch, skin patches, blotchiness, skin sensitivity, discomfort or pain, skin plaques, bleeding, burning, skin lesions, lack of energy or fatigue, hair loss or change in hair growth) they have experienced before entering in the qualitative interview study were reported in this endpoint.

End point type	Primary

End point timeframe:

At Baseline

Notes:

[3] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects				
Redness	17			
Dryness	16			
Itch	14			
Skin patches	14			
Blotchiness	11			
Skin sensitivity	11			
Discomfort or pain	10			
Skin plaques	9			
Bleeding	8			
Burning	8			
Skin lesions	8			
Lack of energy or fatigue	6			
Hair loss or change in hair growth	4			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced The Daily Routine Impact of Early CTCL Stage

End point title	Number of Subjects Who Experienced The Daily Routine Impact of Early CTCL Stage[4]

End point description:

The subjects experience of prior treatment were evaluated with the use of subject interview guide. The number of subjects who experienced the daily routine impact (altered clothing choices, work, social/leisure activities, chores/housework, avoiding sun/sun protection, exercise, wearing gauze/ bandage) before entering in the qualitative interview study were reported in this endpoint.

End point type	Primary

End point timeframe:

At Baseline

Notes:

[4] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects				
Altered Clothing Choices	7			
Work	6			
Social/Leisure Activities	5			
Chores/Housework	4			
Avoiding sun/sun protection	3			
Exercise	2			
Wearing gauze/ bandage	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Emotional Impact of Early CTCL Stage

End point title	Number of Subjects Who Experienced Emotional Impact of Early CTCL Stage[5]

End point description:

The subjects experience of CTCL emotional impact were evaluated with the use of subject interview guide. The number of subjects who experienced of emotional impact (embarrassment/uncomfortable, worry/anxiety/nervousness, stress and frustration, depression, self-identity) before entering in the qualitative interview study were reported in this endpoint.

End point type	Primary

End point timeframe:

At Baseline

Notes:

[5] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects				
Embarrassment/Uncomfortable	9			
Worry/Anxiety/Nervousness	5			
Stress and Frustration	3			

Depression	2			
Self-identity	2			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Sleep Disruption, Financial Burden, Relationship Impact Experience of Early CTCL Stage

End point title	Number of Subjects With Sleep Disruption, Financial Burden, Relationship Impact Experience of Early CTCL Stage[6]

End point description:

The subjects who experienced CTCL related impacts (sleep Disruption, financial burden, relationship) were reported with the use of subject interview guide. The number of subjects who experienced sleep Disruption, financial burden, relationship impacts before entering in the qualitative interview study were reported in this endpoint.

End point type	Primary

End point timeframe:

At Baseline

Notes:

[6] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects				
Sleep disruption	8			
Financial burden	7			
Relationship	6			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Reasons to Enroll in the Clinical Trial

End point title	Number of Subjects With Reasons to Enroll in the Clinical

End point description:

The subjects decision to enroll in the clinical trial were reported with the use of subject interview guide. Subjects who shared their reasons (hope for the effective treatment, doctor's recommendations, desire to contribute in clinical research, family members encouragement, limited treatment options available, worry to loose eligibility for participation) to enroll in the qualitative interview study were reported in this endpoint.

End point type	Primary

End point timeframe:

At Baseline

Notes:

[7] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects				
Hope for the effective treatment	10			
Doctor's recommendations	5			
Desire to contribute in clinical research	4			
Family members encouragement	3			
Limited treatment options available	2			
Worry to loose eligibility for participation	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced New Symptoms After Clinical Trial Entry

End point title	Number of Subjects Who Experienced New Symptoms After Clinical Trial Entry[8]

End point description:

Subject interview guide was used to report any new symptoms they have experienced after clinical trial entry. The number of subjects who recalled any new symptoms that were not previously experienced (skin lesions, redness, burning, bleeding, itch, discomfort or pain, lack of energy, oozing, nausea, fever or chills, flu like symptoms, inflammation, headache) before the entering in the qualitative interview study were reported in this endpoint.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[8] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects				
Skin Lesions	3			
Redness	1			
Burning	3			

Bleeding	2			
Itch	1			
Discomfort or Pain	1			
Lack of Energy	1			
Oozing	1			
Nausea	2			
Fever or Chills	2			
Flu Like Symptoms	2			
Inflammation	1			
Headache	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced New Impacts After Clinical Trial Entry

End point title	Number of Subjects Who Experienced New Impacts After Clinical Trial Entry[9]

End point description:

Subject interview guide was used to report any new impacts they have experienced after clinical trial entry. The number of subjects who recalled any new impacts (work, exercise, relationships, wear gauze or bandage) that were not previously experienced before the entering in the qualitative interview study were reported in this endpoint.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[9] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects				
Work	1			
Exercise	1			
Relationships	1			
Wear Gauze or Bandage	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Change in Symptoms During Clinical

Trial at Week 24

End point title	Number of Subjects Who Experienced Change in Symptoms During Clinical Trial at Week 24[10]

End point description:

The subject interview guide was used to grade their experience of change in symptoms (redness, dryness, itch, skin patches, blotchiness, skin sensitivity, discomfort or pain) into 'improvement, no change and worsening' during trial. The subjects who described their experience of change in symptoms were reported in this endpoint. Here, the number of subjects analysed signifies subjects who were evaluable for this endpoint. Here, n = number of subjects analysed for the specific categories.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[10] - 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: Only Descriptive data was planned to be analyzed.

End point values	CTCL Stage IA	CTCL Stage IB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	8		
Units: subjects				
Redness: Improvement (n=10,8)	7	6		
Redness: No Change (n=10,8)	2	1		
Redness: Worsening (n=10,8)	1	1		
Dryness: Improvement (n=9,7)	2	4		
Dryness: No change (n=9,7)	6	1		
Dryness: Worsening (n=9,7)	1	2		
Itch: Improvement (n=8,7)	5	6		
Itch: No Change (n=8,7)	1	0		
Itch: Worsening (n=8,7)	2	1		
Skin Patches: Improvement (n=8,6)	5	6		
Skin Patches: No Change (n=8,6)	3	0		
Skin Patches: Worsening (n=8,6)	0	0		
Blotchiness: Improvement (n=6,5)	4	3		
Blotchiness: No Change (n=6,5)	2	1		
Blotchiness: Worsening (n=6,5)	0	0		
Skin Sensitivity: Improvement (n=5,6)	2	3		
Skin Sensitivity: No Change (n=5,6)	3	0		
Skin Sensitivity: Worsening (n=5,6)	0	2		
Discomfort or Pain; Improvement(n=5,6)	2	4		
Discomfort or Pain; No Change (n=5,6)	2	0		
Discomfort or Pain; Worsening (n=5,6)	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Change in Impacts During Clinical Trial at Week 24

End point title	Number of Subjects Who Experienced Change in Impacts

	During Clinical Trial at Week 24[11]

End point description:

The subject interview guide was used to grade their experience of change in impacts (Embarrassment/Uncomfortable, Sleep Disruption, Altered Clothing Choices, Financial Burden) in to 'improvement, no change and worsening' during trial. The subjects who described their experience of change in impacts were reported in this endpoint. Here, the number of subjects analysed signifies subjects who were evaluable for this endpoint. Here, n = number of subjects analysed for the specific categories. Change in impacts during trial were not reported for two participants who did not complete up to week 24.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[11] - 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: Only Descriptive data was planned to be analyzed.

End point values	CTCL Stage IA	CTCL Stage IB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	7		
Units: subjects				
Embarrassment or Uncomfortable; Improvement (n=2,7	1	3		
Embarrassment or Uncomfortable; No Change (n=2,7)	0	3		
Embarrassment or Uncomfortable; Worsening (n=2,7)	0	0		
Sleep Disruption; Improvement (n=4,4)	0	2		
Sleep Disruption; No Change (n=4,4)	3	1		
Sleep Disruption; Worsening (n=4,4)	1	0		
Altered Clothing Choices; Improvement (n=2,5)	0	3		
Altered Clothing Choices; No Change (n=2,5)	1	0		
Altered Clothing Choices; Worsening (n=2,5)	0	2		
Financial Burden; Improvement (n=3,4)	0	1		
Financial Burden; No Change (n=3,4)	2	2		
Financial Burden; Worsening (n=3,4)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Change in Symptom Rating (Redness) During Clinical Trial

End point title	Number of Subjects Who Experienced Change in Symptom Rating (Redness) During Clinical Trial[12]

End point description:

The subject interview guide was used to explore their experience of change in redness symptom into 'improvement, no change and worsening' during trial. The subjects rated the improvement into 'better', 'a little better' and 'much better' and the subjects rated the worsening into 'a little worse', 'worse' and 'much worse'. The subjects who described their experience of change in redness symptom rating and meaningful change from baseline were reported in this endpoint. Here, the number of subjects analysed signifies subjects who were evaluable for this endpoint. Here, n = number of subjects analysed for the

specific categories. One subject did not provide the improvement change rating for redness symptom.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[12] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: subjects				
Improvement (A little better) (n=13)	3			
Improvement (Better) (n=13)	6			
Improvement (Much better) (n=13)	3			
Improvement (Meaningful change) (n=13)	13			
Worsening (A little worse) (n=2)	2			
Worsening (Worse) (n=2)	0			
Worsening (Much worse) (n=2)	0			
Worsening (Meaningful change) (n=2)	1			
No change	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Change in Symptom Rating (Dryness) During Clinical Trial

End point title	Number of Subjects Who Experienced Change in Symptom Rating (Dryness) During Clinical Trial[13]

End point description:

The subject interview guide was used to explore their experience of change in dryness symptom into 'improvement, no change and worsening' during trial. The subjects rated the improvement into 'better', 'a little better' and 'much better' and the subjects rated the worsening into 'a little worse', 'worse' and 'much worse'. The subjects who described their experience of change in dryness symptom rating and meaningful change from baseline were reported in this endpoint. The number of subjects analysed signifies subjects who were evaluable for this endpoint. Here, n = number of subjects analysed for the specific categories.

End point type	Primary

End point timeframe:

At week 24

Notes:

[13] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: subjects				
Improvement (A little better) (n=6)	1			
Improvement (Better) (n=6)	3			
Improvement (Much better) (n=6)	2			
Improvement (Meaningful change) (n=6)	6			
Worsening (A little worse) (n=3)	0			
Worsening (Worse) (n=3)	3			
Worsening (Much worse) (n=3)	0			
Worsening- Meaningful change (n=3)	3			
No change	7			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Change in Symptom Rating (Itch) During Clinical Trial

End point title	Number of Subjects Who Experienced Change in Symptom Rating (Itch) During Clinical Trial[14]

End point description:

The subject interview guide was used to explore their experience of change in itch symptom into 'improvement, no change and worsening' during trial. The subjects rated the improvement into 'better', 'a little better' and 'much better' and the subjects rated the worsening into 'a little worse', 'worse' and 'much worse'. The subjects who described their experience of change in itch symptom rating and meaningful change from baseline were reported in this endpoint. Number of subjects analysed signifies subjects who were evaluable for this endpoint. Here, n = number of subjects analysed for the specific categories. One subject did not provide the itch symptom improvement and itch meaningful change rating .

End point type	Primary

End point timeframe:

At Week 24

Notes:

[14] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	11			
Units: subjects				
Improvement (A little better) (n=11)	0			
Improvement (Better) (n=11)	5			
Improvement (Much better) (n=11)	6			

Improvement (Meaningful change) (n=11)	10			
Worsening (A little worse) (n=3)	2			
Worsening (Worse) (n=3)	0			
Worsening (Much worse) (n=3)	1			
Worsening- Meaningful change (n=3)	2			
No change	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Change in Symptom Rating (Skin patches) During Clinical Trial

End point title	Number of Subjects Who Experienced Change in Symptom Rating (Skin patches) During Clinical Trial[15]

End point description:

The subject interview guide was used to explore their experience of change in skin patches symptom into 'improvement, no change and worsening' during trial. The subjects rated the improvement into 'better', 'a little better' and 'much better' and the subjects rated the worsening into 'a little worse', 'worse' and 'much worse'. The subjects who described their experience of change in skin patches symptom rating and meaningful change from baseline were reported in this endpoint. Number of subjects analysed signifies subjects who were evaluable for this endpoint. Here, n = number of subjects analysed for the specific categories.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[15] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	14			
Units: subjects				
Improvement (A little better) (n=11)	3			
Improvement (Better) (n=11)	5			
Improvement (Much better) (n=11)	3			
Improvement (Meaningful change) (n=11)	10			
Worsening (A little worse) (n=0)	0			
Worsening (Worse) (n=0)	0			
Worsening (Much worse) (n=0)	0			
Worsening (Meaningful change) (n=0)	0			
No change	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Change in Symptoms Rating (Blotchiness) During Clinical Trial

End point title	Number of Subjects Who Experienced Change in Symptoms Rating (Blotchiness) During Clinical Trial[16]

End point description:

The subject interview guide was used to explore their experience of change in blotchiness symptom into 'improvement, no change and worsening' during trial. The subjects rated the improvement into 'better', 'a little better' and 'much better' and the subjects rated the worsening into 'a little worse', 'worse' and 'much worse'. The subjects who described their experience of change in blotchiness symptom rating and meaningful change from baseline were reported. Number of subjects analysed signifies subjects who were evaluable for this endpoint. Here, n = number of subjects analysed for the specific categories. Blotchiness improvement change rating was not reported for one subject and two subjects did not provided improvement meaningful change rating.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[16] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	11			
Units: subjects				
Improvement (A little better) (n=7)	2			
Improvement (Better) (n=7)	1			
Improvement (Much better) (n=7)	3			
Improvement (Meaningful change) (n=7)	5			
Worsening (A little worse) (n=0)	0			
Worsening (Worse) (n=0)	0			
Worsening (Much worse) (n=0)	0			
Worsening- Meaningful change (n=0)	0			
No change	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Change in Symptom Rating (Discomfort or Pain) During Clinical Trial

End point title	Number of Subjects Who Experienced Change in Symptom Rating (Discomfort or Pain) During Clinical Trial[17]

End point description:

The subject interview guide was used to explore their experience of change in discomfort or pain symptom into 'improvement, no change and worsening' during trial. The subjects rated the

improvement into 'better', 'a little better' and 'much better' and the subjects rated the worsening into 'a little worse', 'worse' and 'much worse'. The subjects who described their experience of change in discomfort or pain symptom rating and meaningful change from baseline were reported. Number of subjects analysed signifies subjects who were evaluable for this endpoint. Here, n = number of subjects analysed for the specific categories. One subject did not provide improvement meaningful change rating.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[17] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	11			
Units: subjects				
Improvement (A little better) (n=6)	0			
Improvement (Better) (n=6)	2			
Improvement (Much better) (n=6)	4			
Improvement (Meaningful change) (n=6)	5			
Worsening (A little worse) (n=1)	0			
Worsening (Worse) (n=1)	1			
Worsening (Much Worse) (n=1)	0			
Worsening (Meaningful change) (n=1)	1			
No change	2			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Reported Treatment Expectations

End point title	Number of Subjects Who Reported Treatment Expectations[18]

End point description:

The subjects responded that their treatment expectations were 'met or not met' based on the changes observed in the appearance of their skin, worsening of symptoms or lack of long-lasting therapy. The number of subjects who described their treatment expectations were reported in this endpoint. Here, the number of subjects analysed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[18] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	17			
Units: subjects				
Expectations met	12			
Expectations not met	5			

Statistical analyses

No statistical analyses for this end point

Primary: Mean Treatment Satisfaction of Subjects

End point title	Mean Treatment Satisfaction of Subjects[19]

End point description:

The subject interview guide were used explore subjects experience of their level of satisfaction. Subjects rated their level of treatment satisfaction on a scale from zero to 10 where zero indicated "not satisfied at all" and 10 indicated "extremely satisfied". The number of subjects who rated their level of satisfaction were reported in this endpoint. Here, the number of subjects analysed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[19] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: Score on scale				
arithmetic mean (standard deviation)	6.4 (± 3.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Positive and Negative Clinical Trial Experience

End point title	Number of Subjects With Positive and Negative Clinical Trial Experience[20]

End point description:

The subject interview guide was used to explore subjects experience after entering in to the trial. Positive and negative trial experience questioner examples included professionalism, attentiveness, responsiveness, and friendliness of the trial staff, well-organized trial, comfortable interaction with the trial staff, clear guidance and instructions, ease of application of the gel, getting to the appointments.

The subjects who reported positive and negative trial experience were reported in this endpoint. Here, the number of subjects analysed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[20] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects				
Positive Experience	18			
Negative Experience	5			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Recommended Changes in Clinical Trial

End point title	Number of Subjects Who Recommended Changes in Clinical Trial[21]

End point description:

The subject interview guide was used to explore their experience of the trial. Subjects reported their suggestions for changes they would recommend to the trial procedures such as improved laboratory procedures, better coordination with laboratory and medical staff on trial visits, quicker release of lab work, and more education from staff on trial procedures and extension to the trial. The number of subjects who recommended trial changes were reported in this endpoint. Here, the number of subjects analysed signifies subjects who were evaluable for this endpoint.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[21] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	19			
Units: subjects	8			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Who Experienced Change in Symptom Rating (Skin Sensitivity) During Clinical Trial

End point title	Number of Subjects Who Experienced Change in Symptom Rating (Skin Sensitivity) During Clinical Trial[22]

End point description:

The subject interview guide was used to explore their experience of change in skin sensitivity symptom into 'improvement, no change and worsening' during trial. The subjects rated the improvement into 'better', 'a little better' and 'much better' and the subjects rated the worsening into 'a little worse', 'worse' and 'much worse'. The subjects who described their experience of change in skin sensitivity symptom rating and meaningful change from baseline were reported. Number of subjects analysed signifies subjects who were evaluable for this endpoint. Here, n = number of subjects analysed for the specific categories.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[22] - 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: Only Descriptive data was planned to be analyzed.

End point values	Total Number Of Subjects in Exit Interview Sample Study			
Subject group type	Subject analysis set			
Number of subjects analysed	11			
Units: subjects				
Improvement (A little better) (n=5)	0			
Improvement (Better) (n=5)	3			
Improvement (Much better) (n=5)	2			
Improvement (Meaningful change) (n=5)	5			
Worsening (A little worse) (n=2)	1			
Worsening (Worse) (n=2)	1			
Worsening (Much Worse) (n=2)	0			
Worsening (Meaningful change) (n=2)	1			
No change	3			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline up to Week 24

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	CTCL Stage IA

Reporting group description:

Subjects who had early CTCL stage disease (CTCL stage IA) were treated with placebo and resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 1 followed by resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 2. Subjects who treated with placebo in Cycle 1 received resiquimod gel 0.03% during Cycle 2. The two treatment cycles were having duration of 12 weeks of each (eight weeks of treatment plus four weeks of treatment-free) were followed by a 12 week treatment-free follow-up period. Those eligible trial subjects were interviewed after completion of either of the treatment cycle for 3 weeks.

Reporting group title	CTCL Stage IB

Reporting group description:

Subjects who had early CTCL stage disease (CTCL stage IB) were treated with placebo and resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 1 followed by resiquimod gel (0.03% or 0.06%) for eight weeks during Cycle 2. Subjects who treated with placebo in Cycle 1 received resiquimod gel 0.03% during Cycle 2. The two treatment cycles were having duration of 12 weeks of each (eight weeks of treatment plus four weeks of treatment-free) were followed by a 12 weeks treatment-free follow-up period. Those eligible trial participants were interviewed after completion of either of the treatment cycle for 3 weeks.

Serious adverse events	CTCL Stage IA	CTCL Stage IB	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	CTCL Stage IA	CTCL Stage IB	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 11 (100.00%)	8 / 8 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Mycosis fungoides			
subjects affected / exposed	2 / 11 (18.18%)	1 / 8 (12.50%)	
occurrences (all)	3	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	2	
Phlebitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Application site dermatitis			
subjects affected / exposed	1 / 11 (9.09%)	2 / 8 (25.00%)	
occurrences (all)	7	9	
Application site erosion			
subjects affected / exposed	2 / 11 (18.18%)	1 / 8 (12.50%)	
occurrences (all)	3	1	
Application site erythema			
subjects affected / exposed	4 / 11 (36.36%)	1 / 8 (12.50%)	
occurrences (all)	12	1	
Application site pain			
subjects affected / exposed	2 / 11 (18.18%)	0 / 8 (0.00%)	
occurrences (all)	3	0	
Application site papules			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Application site pruritus			
subjects affected / exposed	1 / 11 (9.09%)	2 / 8 (25.00%)	
occurrences (all)	5	5	
Application site ulcer			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	

Application site rash				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Application site vesicles				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Chest pain				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Chills				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Fatigue				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Influenza like illness				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Laceration				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Nausea				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Proctalgia				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Pyrexia				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
Skin ulcer				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		
White blood cell count decreased				
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)		
occurrences (all)	0	1		

Otitis media			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Cough			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Investigations			
Bacterial test positive			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Glucose urine present			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
White blood cell count decreased			
subjects affected / exposed	1 / 11 (9.09%)	1 / 8 (12.50%)	
occurrences (all)	1	1	
Eye infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Blood albumin increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Gamma-Glutamyl transferase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	

Tri-iodothyronine decreased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Application site erosion			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Application site ulcer			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Blood urine present			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Limb injury			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	2	0	
Application site ulcer			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Bundle branch block left			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	0 / 11 (0.00%)	2 / 8 (25.00%)	
occurrences (all)	0	6	

Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Keratitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Diarrhoea			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	2 / 11 (18.18%)	0 / 8 (0.00%)	
occurrences (all)	2	0	
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	2 / 11 (18.18%)	0 / 8 (0.00%)	
occurrences (all)	3	0	
Pruritis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Skin erosion			
subjects affected / exposed	2 / 11 (18.18%)	0 / 8 (0.00%)	
occurrences (all)	2	0	
Papule			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Maematuria			

subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 11 (9.09%)	1 / 8 (12.50%)	
occurrences (all)	1	2	
Aneurysmal bone cyst			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Osteoarthritis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 8 (12.50%)	
occurrences (all)	0	1	
Infections and infestations			
Folliculitis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 8 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 11 (9.09%)	2 / 8 (25.00%)	
occurrences (all)	1	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported