Clinical trial results:
Prospektive, dreiarmige, randomisierte Doppelblind-Studie gemäß MPG und AMG zur Wirksamkeit und Sicherheit der Behandlung der leichten bis moderaten aktinischen Keratose mit einer 5%-igen Kaliumhydroxidlösung (Solcera, Medizinprodukt) versus Placebo sowie untersucherverblindetem Vergleich mit Diclofenac 3% Gel (Solaraze, Arzneimittel)

Summary

EudraCT number	2019-003678-16
Trial protocol	DE
Global end of trial date	26 October 2023

Results information

Result version number	v1 (current)
This version publication date	11 September 2026
First version publication date	11 September 2026

Trial information

Trial identification

Sponsor protocol code	KOHDIAK

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04552327
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Infectopharm Arzneimittel GmbH
Sponsor organisation address	Von-Humboldt-Str. 1, Heppenheim, Germany,
Public contact	Deputy Head of Clinical Research, Infectopharm Arzneimittel GmbH, +49 6252957000, Clinical.Trials@infectopharm.com
Scientific contact	Deputy Head of Clinical Research, Infectopharm Arzneimittel GmbH, +49 6252957000, Clinical.Trials@infectopharm.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	26 October 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 October 2023
Global end of trial reached?	Yes
Global end of trial date	26 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primäres Zielkriterium ist der Therapieerfolg bei der Kontrollvisite nach Ende der Studienbehandlung des Patienten („EOT" - End of treatment, je nach Remissionsverlauf nach Ende der off-Phase des 1., 2. oder 3. Behandlungszyklus für Solcera/Placebo bzw. Tag 60 für Solaraze).

Protection of trial subjects:

In der Solaraze-Gruppe wird mit einem S3-Leitlinien-empfohlenen Arzneimittel behandelt, dessen Wirksamkeit und Sicherheit in kontrollierten klinischen Studien nachgewiesen wurde. Solaraze stellt das aktuell in Deutschland zur Behandlung der AK meistverordnete Präparat dar. Als Nebenwirkungen von Solaraze treten v.a. lokale Hautreaktionen auf, sodass die zu erwartende Wirksamkeit mögliche Risiken überwiegt.
Solcera ist ein zur Behandlung der AK zertifiziertes Medizinprodukt, dessen Wirksamkeit auf Basis von Literaturdaten als mindestens so hoch wie die von Solaraze einzuschätzen ist. Die Verträglichkeit von Solcera hat sich in bisherigen Studien als gut und nicht Therapie-limitierend erwiesen. Nebenwirkungen können vor allem lokale (als Bestandteil des Wirkprinzips erwünschte) und vergleichsweise kurz anhaltende Hautreaktionen sein, die von den Patienten gut toleriert werden.
Unter Placebo ist zwar nicht von einer direkten Wirksamkeit, andererseits kann es durch den natürlichen Verlauf der Erkrankung und begleitende Studienmaßnahmen (UV-Schutz, Vermeidung von intensiver Sonnenexposition und UV-Licht) im Zuge der Studienteilnahme aber auch in der Placebo-Gruppe zu einer Besserung der AK kommen. Vor dem Hintergrund, dass es sich bei der AK um eine chronische und nicht akut behandlungsbedürftige Erkrankung handelt und auch aktuell verfügbare Therapieoptionen keine nachhaltige Heilung ermöglichen, ist bei den hier einzuschließenden leichteren AK-Fällen eine Behandlung mit Placebo vertretbar, zumal jeder Patient engmaschig überwacht wird, sodass der Prüfarzt bei Bedarf Alternativbehandlungen der AK einleiten kann. Zudem erhalten alle Patienten bei Bedarf zum Zeitpunkt der Follow-up-Visite kostenlos eine Packung Solcera. Insofern ist hierdurch in allen Gruppen ein zusätzlicher direkter Individualnutzen gegeben.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 October 2020
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: 630
Worldwide total number of subjects	630
EEA total number of subjects	630

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)	185
From 65 to 84 years	423
85 years and over	22

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Study participants are recruited from the pool of patients presenting with AK at the trial sites in accordance with the inclusion and exclusion criteria. All potentially eligible patients are recorded in a list, the so-called screening list, irrespective of whether they subsequently participate in the study.

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Are arms mutually exclusive?	Yes
Arm title	Solcera

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Solcera
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

Solcera® and Placebo were applied initially two times daily (morning/evening) in the affected area for four weeks. A small amount of solution was to be distributed on every lesion using the provided applicator, so that the entire lesion as well as the surrounding area 1 mm around the lesion was moistened. After that, the treatment was paused for four weeks and the remission was evaluated by the investigator. If the lesions, that were present at treatment start, did not show complete remission, the treatment was to be continued for another four weeks followed by a treatment-free interval of four weeks and reassessment by the investigator (2nd treatment cycle). If again no complete remission of the lesions present at treatment start was achieved, the treatment of the remaining lesions was to be continued for another four weeks followed by a treatment-free interval of four weeks and final reassessment by the investigator (3rd treatment cycle).

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

Solcera® and Placebo were applied initially two times daily (morning/evening) in the affected area for four weeks. A small amount of solution was to be distributed on every lesion using the provided applicator, so that the entire lesion as well as the surrounding area 1 mm around the lesion was moistened. After that, the treatment was paused for four weeks and the remission was evaluated by the investigator. If the lesions, that were present at treatment start, did not show complete remission, the treatment was to be continued for another four weeks followed by a treatment-free interval of four weeks and reassessment by the investigator (2nd treatment cycle). If again no complete remission of the lesions present at treatment start was achieved, the treatment of the remaining lesions was to be continued for another four weeks followed by a treatment-free interval of four weeks and final

reassessment by the investigator (3rd treatment cycle).

Arm title	Solaraze
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Solaraze
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Solcera® and Placebo were applied initially two times daily (morning/evening) in the affected area for four weeks. A small amount of solution was to be distributed on every lesion using the provided applicator, so that the entire lesion as well as the surrounding area 1 mm around the lesion was moistened. After that, the treatment was paused for four weeks and the remission was evaluated by the investigator. If the lesions, that were present at treatment start, did not show complete remission, the treatment was to be continued for another four weeks followed by a treatment-free interval of four weeks and reassessment by the investigator (2nd treatment cycle). If again no complete remission of the lesions present at treatment start was achieved, the treatment of the remaining lesions was to be continued for another four weeks followed by a treatment-free interval of four weeks and final reassessment by the investigator (3rd treatment cycle).

Number of subjects in period 1	Solcera	Placebo	Solaraze
Started	204	212	214
Completed	204	212	214

Period 2	
Period 2 title	Post-baseline visits
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms	
Are arms mutually exclusive?	Yes

Arm title	Solcera
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Solcera
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

Solcera® and Placebo were applied initially two times daily (morning/evening) in the affected area for four weeks. A small amount of solution was to be distributed on every lesion using the provided applicator, so that the entire lesion as well as the surrounding area 1 mm around the lesion was moistened. After that, the treatment was paused for four weeks and the remission was evaluated by the investigator. If the lesions, that were present at treatment start, did not show complete remission, the treatment was to be continued for another four weeks followed by a treatment-free interval of four weeks and reassessment by the investigator (2nd treatment cycle). If again no complete remission of the lesions present at treatment start was achieved, the treatment of the remaining lesions was to be continued for another four weeks followed by a treatment-free interval of four weeks and final reassessment by the investigator (3rd treatment cycle).

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

Solcera® and Placebo were applied initially two times daily (morning/evening) in the affected area for four weeks. A small amount of solution was to be distributed on every lesion using the provided applicator, so that the entire lesion as well as the surrounding area 1 mm around the lesion was moistened. After that, the treatment was paused for four weeks and the remission was evaluated by the investigator. If the lesions, that were present at treatment start, did not show complete remission, the treatment was to be continued for another four weeks followed by a treatment-free interval of four weeks and reassessment by the investigator (2nd treatment cycle). If again no complete remission of the lesions present at treatment start was achieved, the treatment of the remaining lesions was to be continued for another four weeks followed by a treatment-free interval of four weeks and final reassessment by the investigator (3rd treatment cycle).

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

Dosage and administration details:

Solcera® and Placebo were applied initially two times daily (morning/evening) in the affected area for four weeks. A small amount of solution was to be distributed on every lesion using the provided applicator, so that the entire lesion as well as the surrounding area 1 mm around the lesion was moistened. After that, the treatment was paused for four weeks and the remission was evaluated by the investigator. If the lesions, that were present at treatment start, did not show complete remission, the treatment was to be continued for another four weeks followed by a treatment-free interval of four weeks and reassessment by the investigator (2nd treatment cycle). If again no complete remission of the lesions present at treatment start was achieved, the treatment of the remaining lesions was to be continued for another four weeks followed by a treatment-free interval of four weeks and final reassessment by the investigator (3rd treatment cycle).

Arm title	Placebo
Arm description: -	
Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous solution
Routes of administration	Topical use

Dosage and administration details:

Solcera® and Placebo were applied initially two times daily (morning/evening) in the affected area for four weeks. A small amount of solution was to be distributed on every lesion using the provided applicator, so that the entire lesion as well as the surrounding area 1 mm around the lesion was moistened. After that, the treatment was paused for four weeks and the remission was evaluated by the investigator. If the lesions, that were present at treatment start, did not show complete remission, the treatment was to be continued for another four weeks followed by a treatment-free interval of four weeks and reassessment by the investigator (2nd treatment cycle). If again no complete remission of the lesions present at treatment start was achieved, the treatment of the remaining lesions was to be continued for another four weeks followed by a treatment-free interval of four weeks and final reassessment by the investigator (3rd treatment cycle).

Arm title	Solaraze

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Solaraze
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical use

Dosage and administration details:

Solcera® and Placebo were applied initially two times daily (morning/evening) in the affected area for four weeks. A small amount of solution was to be distributed on every lesion using the provided applicator, so that the entire lesion as well as the surrounding area 1 mm around the lesion was moistened. After that, the treatment was paused for four weeks and the remission was evaluated by the investigator. If the lesions, that were present at treatment start, did not show complete remission, the treatment was to be continued for another four weeks followed by a treatment-free interval of four weeks and reassessment by the investigator (2nd treatment cycle). If again no complete remission of the lesions present at treatment start was achieved, the treatment of the remaining lesions was to be continued for another four weeks followed by a treatment-free interval of four weeks and final reassessment by the investigator (3rd treatment cycle).

Number of subjects in period 2	Solcera	Placebo	Solaraze
Started	204	212	214
Completed	185	194	198
Not completed	19	18	16
Consent withdrawn by subject	4	8	4
Intolerability reaction	3	2	4
Adverse event	4	3	4
Other reason	6	1	2
Treatment interruption	1	-	-
Lack of efficacy	1	4	1
SARS-CoV-2	-	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	630	630	
Age categorical			
Age (years)			
Units: Subjects			
Adults	630	630	
Age continuous			
Age (years)			
Units: years			
arithmetic mean	69.8		
standard deviation	± 9.4	-	
Gender categorical			
Units: Subjects			
Female	189	189	
Male	441	441	

End points

End points reporting groups

Reporting group title	Solcera
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Solaraze
Reporting group description: -	
Reporting group title	Solcera
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Solaraze
Reporting group description: -	

Primary: Treatment Success (FA)

End point title	Treatment Success (FA)

End point description:

Treatment success, defined as complete, dermatoscopically confirmed remission of all initial actinic keratosis (AK) lesions identified at treatment start that have been treated with the investigational product („Complete Clearance“)

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus “Baseline-Observation-Carried-Forward” [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Primary

End point timeframe:

At the control visit at the end of treatment ("EOT", i.e. for Solcera/Placebo at the end of cycle 1, 2 or 3 (each cycle is 56 days, number of cycles depends on course of remission), for Solaraze day 60)

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: participants	90	47	50	

Statistical analyses

Statistical analysis title	Superiority Solcera/Placebo
Comparison groups	Solcera v Placebo v Solaraze

Number of subjects included in analysis	614
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Fisher exact

Statistical analysis title	Superiority Solcera/Solaraze
Comparison groups	Solcera v Placebo v Solaraze
Number of subjects included in analysis	614
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Fisher exact

Primary: Treatment Success (PP)

End point title	Treatment Success (PP)

End point description:

Treatment success, defined as complete, dermatoscopically confirmed remission of all initial actinic keratosis (AK) lesions identified at treatment start that have been treated with the investigational product („Complete Clearance")

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Primary

End point timeframe:

At the control visit at the end of treatment („EOT", i.e. for Solcera/Placebo at the end of cycle 1, 2 or 3 (each cycle is 56 days, number of cycles depends on course of remission), for Solaraze day 60)

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	183	180	
Units: participants	76	44	37	

Statistical analyses

Statistical analysis title	Non-inferiority of Solcera to Solaraze
Comparison groups	Solcera v Placebo v Solaraze

Number of subjects included in analysis	530
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Odds ratio (OR)
Point estimate	0.31
Confidence interval	
level	95 %
sides	1-sided
upper limit	0.497

Secondary: Treatment Success (FA)

End point title	Treatment Success (FA)

End point description:

Treatment success, defined as complete, dermatoscopically confirmed remission of all initial AK lesions identified at treatment start that have been treated with the investigational product („Complete Clearance")

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

For Solaraze at day 90, for Solcera/Placebo at EOT

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: participants	90	47	82	

Statistical analyses

No statistical analyses for this end point

Secondary: (Healing) status of inital AK lesions

End point title	(Healing) status of inital AK lesions

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At end of treatment (EOT)

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Lesions				
number (not applicable)				
Proliferating	25	45	23	
Unchanged/stable	56	153	84	
In remission/partial remisson	108	152	224	
Complete remission	408	254	302	
Relapse	31	33	25	
Size 0-5 mm	524	438	494	
Size 6-10 mm	83	163	139	
Size 11-15 mm	15	34	23	
Size 16-20 mm	6	2	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall number of AK lesions

End point title	Overall number of AK lesions

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus “Baseline-Observation-Carried-Forward” [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: participants				
0 Lesions	95	49	52	
1 Lesions	43	48	68	
2 Lesions	26	40	28	
3 Lesions	23	33	26	
4 Lesions	4	19	26	
5 Lesions	8	16	10	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Size of AK Lesions

End point title	Mean Size of AK Lesions

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At OT

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: mm				
arithmetic mean (standard deviation)	2.0 (± 3.1)	3.8 (± 3.3)	3.4 (± 3.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Success

End point title	Treatment Success

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT

End point values	Solcera	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	199	205		
Units: participants				
Visit 8 weeks	31	12		
Visit 16 weeks	58	29		
Visit 24 weeks	90	47		

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Success

End point title	Treatment Success

End point description:

At all control/follow-up visits with evaluation of lesions (i.e. for Solcera/Placebo 8 weeks (+ potentially 16 weeks) and 24 weeks after treatment start; for Solaraze Day 30, Day 60, Day 90, 24 weeks)

End point type	Secondary

End point timeframe:

Day 30, Day 60, Day 90,

End point values	Solaraze			
Subject group type	Reporting group			
Number of subjects analysed	210			
Units: participants				
Visit 30 days	19			
Visit 60 days	50			
Visit 90 days	82			

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment Success

End point title	Treatment Success

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus “Baseline-Observation-Carried-Forward” [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT an Follow-up 24 weeks

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: participants				
EOT	90	47	50	
Follow-up 24 weeks	74	43	86	

Statistical analyses

No statistical analyses for this end point

Secondary: Partial Clearance

End point title	Partial Clearance

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: participants	108	57	67	

Statistical analyses

No statistical analyses for this end point

Secondary: Reduction of AK lesions number

End point title	Reduction of AK lesions number

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: percentage				
arithmetic mean (standard deviation)	65.6 (± 38.7)	38.3 (± 41.1)	43.8 (± 40.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Clinical Response

End point title	Clinical Response

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: participants	161	110	129	

Statistical analyses

No statistical analyses for this end point

Secondary: Lesions-based Treatment Success (without consideration of relapses)

End point title	Lesions-based Treatment Success (without consideration of relapses)

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Lesions				
number (not applicable)	439	287	327	

Statistical analyses

No statistical analyses for this end point

Secondary: Lesion-based Treatment Success (with consideration of relapses)

End point title	Lesion-based Treatment Success (with consideration of relapses)

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

tbd

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Lesions				
number (not applicable)	408	254	302	

Statistical analyses

No statistical analyses for this end point

Secondary: Patients with relapse

End point title	Patients with relapse

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all

patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At Follow-up

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: participants	16	4	21	

Statistical analyses

No statistical analyses for this end point

Secondary: Lesions with relapse

End point title	Lesions with relapse

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

Analysed at the follow-up visit 24 weeks after treatment start for the time period between treatment start and the follow-up visit

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Lesions				
number (not applicable)	21	7	66	

Statistical analyses

No statistical analyses for this end point

Secondary: Efficacy assessment by physician

End point title	Efficacy assessment by physician

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT (i.e. for Solcera/Placebo at the end of cycle 1, 2 or 3 (each cycle is 56 days, number of cycles depends on course of remission), for Solaraze day 60) and at the follow-up visit 24 weeks after treatment start

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Participants				
very good	79	42	60	
good	55	49	80	
satisfactory	28	36	36	
sufficient	15	17	11	
poor	7	19	12	
insufficient	6	36	2	
missing	9	6	9	

Statistical analyses

No statistical analyses for this end point

Secondary: Efficacy Assessment by Patient

End point title	Efficacy Assessment by Patient

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT (i.e. for Solcera/Placebo at the end of cycle 1, 2 or 3 (each cycle is 56 days, number of cycles depends on course of remission), for Solaraze day 60) and at the follow-up visit 24 weeks after treatment start

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Participant				
very good	77	35	56	
good	54	56	85	
satisfactory	34	41	39	
sufficient	14	18	11	
poor	9	16	7	
insufficient	2	33	3	
missing	9	6	9	

Statistical analyses

No statistical analyses for this end point

Secondary: Tolerability assessment by physician

End point title	Tolerability assessment by physician

End point description:

Safety-evaluable data set (all randomised patients who received the study medication and for whom an application of the study medication at least cannot be ruled out)

End point type	Secondary

End point timeframe:

At EOT (i.e. for Solcera/Placebo at the end of cycle 1, 2 or 3 (each cycle is 56 days, number of cycles depends on course of remission), for Solaraze day 60) and at the follow-up visit 24 weeks after treatment start

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Participants				
very good	95	118	116	
good	75	65	60	
satisfactory	16	10	19	
sufficient	1	3	5	
poor	2	2	4	
insufficient	1	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Tolerability assessment by patient

End point title	Tolerability assessment by patient

End point description:

Safety-evaluable data set (all randomised patients who received the study medication and for whom an application of the study medication at least cannot be ruled out)

End point type	Secondary

End point timeframe:

At EOT (i.e. for Solcera/Placebo at the end of cycle 1, 2 or 3 (each cycle is 56 days, number of cycles depends on course of remission), for Solaraze day 60) and at the follow-up visit 24 weeks after treatment start

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	190	199	205	
Units: Participants				
very good	74	119	108	
good	90	58	64	
satisfactory	19	16	17	
sufficient	3	4	8	
poor	2	0	4	
in sufficient	2	2	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall assessment by physician

End point title	Overall assessment by physician

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus “Baseline-Observation-Carried-Forward” [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT (i.e. for Solcera/Placebo at the end of cycle 1, 2 or 3 (each cycle is 56 days, number of cycles depends on course of remission), for Solaraze day 60) and at the follow-up visit 24 weeks after treatment start

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Participants				
very good	75	40	55	
good	65	58	92	
satisfactory	28	39	35	

sufficient	9	20	14	
poor	9	28	4	
insufficient	2	14	1	
missing	11	6	9	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall assessment by patient

End point title	Overall assessment by patient

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

At EOT (i.e. for Solcera/Placebo at the end of cycle 1, 2 or 3 (each cycle is 56 days, number of cycles depends on course of remission), for Solaraze day 60) and at the follow-up visit 24 weeks after treatment start

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Participants				
very good	69	38	57	
good	74	64	96	
satisfactory	28	37	33	
sufficient	9	26	9	
poor	7	29	5	
insufficient	1	5	1	
missing	11	6	9	

Statistical analyses

No statistical analyses for this end point

Secondary: Adverse Events, Serious Adverse Events, Adverse Reactions

End point title	Adverse Events, Serious Adverse Events, Adverse Reactions

End point description:

Safety-evaluable data set (all randomised patients who received the study medication and for whom an application of the study medication at least cannot be ruled out)

End point type	Secondary

End point timeframe:

In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	212	214	
Units: Treatment-emergent Events				
number (not applicable)				
Treatmet-emergent Adverse Events (TEAE)	293	123	177	
Treatment-emergent Serious Adverse Events	21	16	13	
Treatment-emergent Adverse Drug Reaction	206	34	106	

Statistical analyses

No statistical analyses for this end point

Secondary: Dropouts

End point title	Dropouts

End point description:

Safety-evaluable data set (all randomised patients who received the study medication and for whom an application of the study medication at least cannot be ruled out)

End point type	Secondary

End point timeframe:

In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	212	214	
Units: Participants				
Informed consent withdrawn	4	8	4	
Adverse event	4	3	4	
Interruption treatment >10 consecutive application	1	0	0	
Intolerability reaction	3	2	4	
Lack of efficacy	1	4	1	
Discontinuation due to SARS-CoV-2	0	0	1	
Other reasons	6	1	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Compliance

End point title	Compliance

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

Analysed for the respective time period of scheduled product application, i.e. Day 0 until Day 60 for Solaraze and 1-3x 28 days (depeding on number of cycles) for Solcera/Placebo

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	199	205	210	
Units: Percentage of comliance				
arithmetic mean (standard deviation)	101.1 (± 16.8)	98.4 (± 11.5)	94.8 (± 12.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment success (PP)

End point title	Treatment success (PP)

End point description:

Full-analysis data set (at least one IMP application, at least one post-baseline value for the primary endpoint; plus "Baseline-Observation-Carried-Forward" [BOCF] of primary efficacy variable for all patients who (i) withdrew due to lacking tolerability and applied the study medication at least once or (ii) withdrew due to lacking efficacy (e.g. also other AK therapies of the lesions used in the initially treated area) and applied the study medication for at least 7 days

End point type	Secondary

End point timeframe:

For Solaraze at day 90, for Solcera/Placebo at EOT

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	183	180	
Units: Participants	76	44	63	

Statistical analyses

No statistical analyses for this end point

Secondary: Adverse Events, Serious Adverse Events, Adverse Reactions

End point title	Adverse Events, Serious Adverse Events, Adverse Reactions

End point description:

Safety-evaluable data set (all randomised patients who received the study medication and for whom an application of the study medication at least cannot be ruled out)

End point type	Secondary

End point timeframe:

In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)

End point values	Solcera	Placebo	Solaraze	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	212	214	
Units: Prticipants				
with treatment-emergent Adverse Event (TEAE)	113	78	92	
with treatment-emergent Serious Adverse Event	17	12	11	
with treatment-emergent Serious Drug Reaction (ADR	78	23	47	
with ADR not part of expected/desired reaction	6	4	5	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
6 months	
Adverse event reporting additional description:	
For non-serious adverse events please see respective endpoints	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups	
Reporting group title	Solcera
Reporting group description:	
In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)	
Reporting group title	Placebo
Reporting group description:	
In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)	
Reporting group title	Solaraze
Reporting group description:	
In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)	

Serious adverse events	Solcera	Placebo	Solaraze
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 204 (8.33%)	12 / 212 (5.66%)	11 / 214 (5.14%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	9 / 204 (4.41%)	6 / 212 (2.83%)	4 / 214 (1.87%)
occurrences causally related to treatment / all	0 / 10	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	2 / 204 (0.98%)	1 / 212 (0.47%)	0 / 214 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		

subjects affected / exposed	2 / 204 (0.98%)	0 / 212 (0.00%)	0 / 214 (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
Malignant melanoma in situ	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	1 / 212 (0.47%)	0 / 214 (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
Vascular disorders			
Vascular stenosis	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	1 / 204 (0.49%)	0 / 212 (0.00%)	0 / 214 (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
Peripheral arterial occlusive disease	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	0 / 212 (0.00%)	1 / 214 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	0 / 212 (0.00%)	2 / 214 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	1 / 204 (0.49%)	0 / 212 (0.00%)	0 / 214 (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
Epistaxis	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	0 / 212 (0.00%)	1 / 214 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		

subjects affected / exposed	0 / 204 (0.00%)	1 / 212 (0.47%)	0 / 214 (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
Psychiatric disorders			
Somatic symptom disorder	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	0 / 212 (0.00%)	1 / 214 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Craniocerebral injury	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	0 / 212 (0.00%)	1 / 214 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	1 / 212 (0.47%)	0 / 214 (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
Congenital, familial and genetic disorders			
Skeletal dysplasia	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	1 / 212 (0.47%)	0 / 214 (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
Cardiac disorders			
Myocardial infarction	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	2 / 204 (0.98%)	0 / 212 (0.00%)	0 / 214 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Rheumatic heart disease	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	1 / 212 (0.47%)	0 / 214 (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
Eye disorders			

Visual impairment	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	0 / 212 (0.00%)	1 / 214 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	1 / 212 (0.47%)	0 / 214 (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
Gastrointestinal disorders			
Inguinal hernia	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	0 / 212 (0.00%)	1 / 214 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	1 / 204 (0.49%)	1 / 212 (0.47%)	0 / 214 (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
Skin and subcutaneous tissue disorders			
Hypertrophic scar	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	1 / 204 (0.49%)	0 / 212 (0.00%)	0 / 214 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	1 / 204 (0.49%)	0 / 212 (0.00%)	0 / 214 (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
Infections and infestations			
Influenza	Additional description: In the time period between start of treatment and the follow-up visit (24 weeks after treatment start)		
subjects affected / exposed	0 / 204 (0.00%)	1 / 212 (0.47%)	0 / 214 (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

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Solcera	Placebo	Solaraze
Total subjects affected by non-serious adverse events			
subjects affected / exposed	86 / 204 (42.16%)	47 / 212 (22.17%)	58 / 214 (27.10%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 204 (0.49%)	1 / 212 (0.47%)	1 / 214 (0.47%)
occurrences (all)	1	1	1
Seborrhoeic keratosis			
subjects affected / exposed	4 / 204 (1.96%)	2 / 212 (0.94%)	5 / 214 (2.34%)
occurrences (all)	4	2	5
Injury, poisoning and procedural complications			
not appicable			
subjects affected / exposed	3 / 204 (1.47%)	4 / 212 (1.89%)	6 / 214 (2.80%)
occurrences (all)	3	4	6
Vascular disorders			
not applicable			
subjects affected / exposed	5 / 204 (2.45%)	4 / 212 (1.89%)	2 / 214 (0.93%)
occurrences (all)	5	4	2
General disorders and administration site conditions			
Application site erythema			
subjects affected / exposed	53 / 204 (25.98%)	10 / 212 (4.72%)	29 / 214 (13.55%)
occurrences (all)	65	10	29
Application site pain			
subjects affected / exposed	45 / 204 (22.06%)	8 / 212 (3.77%)	7 / 214 (3.27%)
occurrences (all)	66	8	7
Application site scab			
subjects affected / exposed	29 / 204 (14.22%)	3 / 212 (1.42%)	21 / 214 (9.81%)
occurrences (all)	39	3	22
Application site pruritus			

subjects affected / exposed	5 / 204 (2.45%)	5 / 212 (2.36%)	18 / 214 (8.41%)
occurrences (all)	5	5	18
Application site exfoliation			
subjects affected / exposed	10 / 204 (4.90%)	3 / 212 (1.42%)	14 / 214 (6.54%)
occurrences (all)	13	3	14
Application site erosion			
subjects affected / exposed	5 / 204 (2.45%)	0 / 212 (0.00%)	2 / 214 (0.93%)
occurrences (all)	6	0	2
Eye disorders			
not applicable			
subjects affected / exposed	1 / 204 (0.49%)	5 / 212 (2.36%)	2 / 214 (0.93%)
occurrences (all)	1	5	3
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	4 / 204 (1.96%)	2 / 212 (0.94%)	1 / 214 (0.47%)
occurrences (all)	4	2	1
Musculoskeletal and connective tissue disorders			
not applicable			
subjects affected / exposed	8 / 204 (3.92%)	3 / 212 (1.42%)	1 / 214 (0.47%)
occurrences (all)	8	3	1
Infections and infestations			
COVID-19			
subjects affected / exposed	4 / 204 (1.96%)	10 / 212 (4.72%)	2 / 214 (0.93%)
occurrences (all)	4	10	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