Clinical trial results:
A Phase 3, 4-Week, Parallel Group, Double Blind, Vehicle-Controlled Study of the Safety and Efficacy of ARQ-151 Cream 0.05% Administered QD in Subjects with Atopic Dermatitis

Summary

EudraCT number	2021-006903-14
Trial protocol	PL
Global end of trial date	01 June 2023

Results information

Result version number	v1 (current)
This version publication date	18 April 2026
First version publication date	18 April 2026

Trial information

Trial identification

Sponsor protocol code	ARQ-151-315

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04804605
WHO universal trial number (UTN)	-
Other trial identifiers	IND: 135681

Notes:

Sponsors

Sponsor organisation name	Arcutis Biotherapeutics, Inc.
Sponsor organisation address	3027 Townsgate Rd #300, Westlake Village, CA, United States, 91361
Public contact	Arcutis Medical Information, Arcutis Biotherapeutics, Inc., +1 8054185006, information@arcutis.com
Scientific contact	Arcutis Medical Information, Arcutis Biotherapeutics, Inc., +1 8054185006, information@arcutis.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	01 June 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 June 2023
Global end of trial reached?	Yes
Global end of trial date	01 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study assessed the safety and efficacy of ARQ-151 cream vs vehicle applied once a day for 4 weeks by subjects with atopic dermatitis (eczema).

Protection of trial subjects:

This study was conducted in accordance with the Declaration of Helsinki, ICH Good Clinical Practice, and all applicable local laws/regulation.

Background therapy: -

Evidence for comparator: -

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

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 447
Country: Number of subjects enrolled	Poland: 152
Country: Number of subjects enrolled	Canada: 53
Worldwide total number of subjects	652
EEA total number of subjects	152

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)	652
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants who were 2 to 5 years of age at Screening with atopic dermatitis (AD) were recruited in Canada, Poland, and the United States.

Pre-assignment

Screening details:

Male and female participants 2 to 5 years of age with atopic dermatitis for at least 6 weeks were recruited.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Roflumilast Cream 0.05%

Arm description:

Participants applied roflumilast cream 0.05% qd for 4 weeks.

Arm type	Experimental
Investigational medicinal product name	Roflumilast Cream 0.05%
Investigational medicinal product code	
Other name	ARQ-151
Pharmaceutical forms	Cream
Routes of administration	Topical

Dosage and administration details:

Roflumilast cream for topical application.

Arm title	Vehicle Cream

Arm description:

Participants applied vehicle cream qd for 4 weeks.

Arm type	Placebo
Investigational medicinal product name	Vehicle Cream
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Topical

Dosage and administration details:

Vehicle cream matched to roflumilast cream for topical application.

Number of subjects in period 1	Roflumilast Cream 0.05%	Vehicle Cream
Started	437	215
Completed	410	192
Not completed	27	23
Physician decision	2	1
Consent withdrawn by subject	11	10
Adverse event, non-fatal	5	4
Lost to follow-up	5	4
Lack of efficacy	4	4

Baseline characteristics

Reporting groups	
Reporting group title	Roflumilast Cream 0.05%
Reporting group description:	
Participants applied roflumilast cream 0.05% qd for 4 weeks.	
Reporting group title	Vehicle Cream
Reporting group description:	
Participants applied vehicle cream qd for 4 weeks.	

Reporting group values	Roflumilast Cream 0.05%	Vehicle Cream	Total
Number of subjects	437	215	652
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	437	215	652
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	3.3	3.2	
standard deviation	± 1.09	± 1.10	-
Gender categorical Units: Subjects			
Female	211	99	310
Male	226	116	342
Race Units: Subjects			
White	295	156	451
Black or African American	68	32	100
Asian	37	17	54
Multiple	28	4	32
Other	8	4	12
American Indian or Alaska native	1	2	3
Ethnicity Units: Subjects			
Hispanic or Latino	82	31	113
Not Hispanic or Latino	352	184	536
Not reported	3	0	3

End points

End points reporting groups	
Reporting group title	Roflumilast Cream 0.05%
Reporting group description:	
Participants applied roflumilast cream 0.05% qd for 4 weeks.	
Reporting group title	Vehicle Cream
Reporting group description:	
Participants applied vehicle cream qd for 4 weeks.	

Primary: Achievement of Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) Success at Week 4

End point title	Achievement of Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) Success at Week 4
End point description:	
The percentage of participants with vIGA-AD success at Week 4 is presented. The vIGA-AD is a static evaluation of qualitative overall AD severity with five severity grades (reported as score of 0 'clear' to 4 'severe' with higher scores indicating greater symptom severity. vIGA success was defined as score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline. All randomized participants are included, 1 participant in the Roflumilast Cream 0.05% arm was inadvertently treated prior to randomization and thus excluded from analysis.	
End point type	Primary
End point timeframe:	
Week 4	

End point values	Roflumilast Cream 0.05%	Vehicle Cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	436	215		
Units: percentage of participants				
number (confidence interval 97.5%)	25.4 (20.95 to 30.34)	10.7 (6.77 to 16.45)		

Statistical analyses

Statistical analysis title	vIGA Success at Week 4
Comparison groups	Roflumilast Cream 0.05% v Vehicle Cream
Number of subjects included in analysis	651
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [1]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.89

Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	1.648
upper limit	5.064

Notes:

[1] - Stratified by randomized baseline vIGA-AD with multiple imputation of missing observations

Secondary: Achievement of vIGA-AD Success at Week 4 in Participants With 'Moderate' Baseline vIGA-AD

End point title	Achievement of vIGA-AD Success at Week 4 in Participants With 'Moderate' Baseline vIGA-AD

End point description:

The percentage of participants with vIGA-AD success at Week 4 who had 'moderate' vIGA-AD score (vIGA score of 3) at baseline is presented. The vIGA-AD is a static evaluation of qualitative overall AD severity with five severity grades (reported as score of 0 'clear' to 4 'severe' with higher scores indicating greater symptom severity. vIGA-AD success was defined as score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline in participants with moderate vIGA-AD baseline. All randomized participants with a baseline vIGA score of 'moderate' are included.

End point type	Secondary

End point timeframe:

Week 4

End point values	Roflumilast Cream 0.05%	Vehicle Cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	333	171		
Units: percentage of participants				
number (confidence interval 97.5%)	27.7 (22.55 to 33.62)	11.0 (6.67 to 17.73)		

Statistical analyses

Statistical analysis title	vIGA Success at Week 4 'Moderate' baseline scores
Comparison groups	Roflumilast Cream 0.05% v Vehicle Cream
Number of subjects included in analysis	504
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [2]
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Point estimate	3.1
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	1.662
upper limit	5.772

Notes:

[2] - Multiple imputation of missing observations

Secondary: Achievement of 75% Reduction in the Eczema Area and Severity Index(EASI-75) at Week 4 in Participants With 'Moderate' Baseline vIGA

End point title	Achievement of 75% Reduction in the Eczema Area and Severity Index(EASI-75) at Week 4 in Participants With 'Moderate' Baseline vIGA

End point description:

The percentage of participants with a moderate baseline vIGA-AD score who achieved EASI-75 is presented. EASI is an instrument to measure the severity and extent of AD. The body is first divided into 4 areas: head (10% of skin), arms (20%), trunk (30%), and legs (40%). Then, the area affected is scored from 0 (0% involvement) to 6 (90-100% involvement), and severity is scored from 0 ('none') to 3 ('severe'). EASI combines the area affected and severity ratings to get a final composite score ranging from 0 (no disease) to 72 (maximal disease). Note that palms and soles were treated as appropriate but were not counted towards any measurements of EASI. All randomized participants are included, with the exception of 1 participant in the Roflumilast Cream 0.05% arm who was inadvertently treated prior to randomization and thus excluded from analysis.

End point type	Secondary

End point timeframe:

Week 4

End point values	Roflumilast Cream 0.05%	Vehicle Cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	436	215		
Units: percentage of participants				
number (confidence interval 97.5%)	39.4 (34.21 to 44.81)	20.6 (15.06 to 27.55)		

Statistical analyses

Statistical analysis title	EASI-75 at Week 4
Comparison groups	Roflumilast Cream 0.05% v Vehicle Cream
Number of subjects included in analysis	651
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.47
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	1.578
upper limit	3.87

Notes:

[3] - Stratified by randomized baseline vIGA-AD with multiple imputation of missing observations

Secondary: Achievement of vIGA-AD Score of 'Clear' or 'Almost Clear' at Week 4

End point title	Achievement of vIGA-AD Score of 'Clear' or 'Almost Clear' at Week 4

End point description:

The percentage of participants with vIGA-AD score of 'clear' or 'almost clear' at Week 4 is presented. The vIGA is a static evaluation of qualitative overall AD severity with five severity grades (reported as score of 0 'clear' to 4 'severe' with higher scores indicating greater symptom severity. All randomized participants are included, 1 participant in the Roflumilast Cream 0.05% arm was inadvertently treated prior to randomization and thus excluded from analysis.

End point type	Secondary

End point timeframe:

Week 4

End point values	Roflumilast Cream 0.05%	Vehicle Cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	436	215		
Units: percentage of participant				
number (confidence interval 97.5%)	35.4 (30.39 to 40.66)	14.6 (9.94 to 20.86)		

Statistical analyses

Statistical analysis title	vIGA Score of 'Clear' or 'Almost Clear' at Week 4
Comparison groups	Roflumilast Cream 0.05% v Vehicle Cream
Number of subjects included in analysis	651
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.29
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	1.98
upper limit	5.475

Notes:

[4] - Stratified by randomized baseline vIGA-AD with multiple imputation of missing observations

Secondary: Achievement of vIGA-AD Success at Week 2

End point title	Achievement of vIGA-AD Success at Week 2

End point description:

The percentage of participants with vIGA-AD success at Week 2 is presented. The vIGA-AD is a static evaluation of qualitative overall AD severity with five severity grades (reported as score of 0 'clear' to 4 'severe' with higher scores indicating greater symptom severity. vIGA success was defined as score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline. All randomized participants are included, 1 participant in the Roflumilast Cream 0.05% arm was inadvertently treated prior to randomization and thus excluded from analysis.

End point type	Secondary

End point timeframe:

Week 2

End point values	Roflumilast Cream 0.05%	Vehicle Cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	436	215		
Units: percentage of participants				
number (confidence interval 97.5%)	21.2 (17.13 to 25.98)	6.8 (3.85 to 11.88)		

Statistical analyses

Statistical analysis title	vIGA Success at Week 2
Comparison groups	Roflumilast Cream 0.05% v Vehicle Cream
Number of subjects included in analysis	651
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [5]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.74
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	1.912
upper limit	7.313

Notes:

[5] - Stratified by baseline vIGA-AD with multiple imputation of missing observations

Secondary: Achievement of vIGA-AD Success at Week 1

End point title	Achievement of vIGA-AD Success at Week 1

End point description:

The percentage of participants with vIGA-AD success at Week 1 is presented. The vIGA-AD is a static evaluation of qualitative overall AD severity with five severity grades (reported as score of 0 'clear' to 4'severe' with higher scores indicating greater symptom severity. vIGA-AD success was defined as score of 'clear' or 'almost clear' plus a 2-gradeimprovement from baseline. All randomized participants are included, 1 participant in the Roflumilast Cream 0.05%arm was inadvertently treated prior to randomization and thus excluded from analysis.

End point type	Secondary

End point timeframe:

Week 1

End point values	Roflumilast Cream 0.05%	Vehicle Cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	436	215		
Units: Percentage of Participants				
number (confidence interval 97.5%)	9.4 (6.72 to 13.02)	0.9 (0.22 to 3.88)		

Statistical analyses

Statistical analysis title	vIGA-AD Success at Week 1
Comparison groups	Roflumilast Cream 0.05% v Vehicle Cream
Number of subjects included in analysis	651
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [6]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	11.44
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	2.216
upper limit	59.101

Notes:

[6] - Stratified by randomized baseline vIGA-AD with multiple imputation of missing data

Secondary: Achievement of vIGA-AD of 'Clear' or 'Almost Clear' at Week 2

End point title	Achievement of vIGA-AD of 'Clear' or 'Almost Clear' at Week 2

End point description:

The percentage of participants with vIGA-AD score of 'clear' or 'almost clear' at Week 2 is presented. The vIGA-AD is a static evaluation of qualitative overall AD severity with five severity grades (reported as score of 0 'clear' to 4 'severe' with higher scores indicating greater symptom severity). All randomized participants are included, 1 participant in the Roflumilast Cream 0.05%arm was inadvertently treated prior to randomization and thus excluded from analysis

End point type	Secondary

End point timeframe:

Week 2

End point values	Roflumilast Cream 0.05%	Vehicle Cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	436	215		
Units: Percentage of Participants				
number (confidence interval 97.5%)	30.4 (25.67 to 35.58)	10.6 (6.74 to 16.42)		

Statistical analyses

Statistical analysis title	vIGA-AD of Clear or Almost Clear at Week 2
Comparison groups	Vehicle Cream v Roflumilast Cream 0.05%
Number of subjects included in analysis	651
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.8
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	2.137
upper limit	6.761

Notes:

[7] - Stratified by randomized baseline vIGA-AD with multiple imputation of missing data

Secondary: Achievement of vIGA-AD of 'Clear' or 'Almost Clear' at Week 1

End point title	Achievement of vIGA-AD of 'Clear' or 'Almost Clear' at Week 1

End point description:

The percentage of participants with vIGA-AD score of 'clear' or 'almost clear' at Week 1 is presented. The vIGA-AD is a static evaluation of qualitative overall AD severity with five severity grades (reported as score of 0 'clear' to 4 'severe' with higher scores indicating greater symptom severity). All randomized participants are included, 1 participant in the Roflumilast Cream 0.05%arm was inadvertently treated prior to randomization and thus excluded from analysis.

End point type	Secondary

End point timeframe:

Week 1

End point values	Roflumilast Cream 0.05%	Vehicle Cream		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	436	215		
Units: Percentage of Participants				
number (confidence interval 97.5%)	17.00 (13.32 to 21.37)	3.7 (1.73 to 7.83)		

Statistical analyses

Statistical analysis title	vIGA-AD of Clear or Almost Clear at Week 1
Comparison groups	Roflumilast Cream 0.05% v Vehicle Cream
Number of subjects included in analysis	651
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [8]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	5.75
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	2.342
upper limit	14.113

Notes:

[8] - Stratified by baseline vIGA-AD with multiple imputation of missing data

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Up to ~6 weeks	
Adverse event reporting additional description:	
All treated participants are included.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups	
Reporting group title	Roflumilast Cream 0.05%
Reporting group description:	
Participants applied roflumilast cream 0.05% qd for 4 weeks.	
Reporting group title	Vehicle Cream
Reporting group description:	
Participants applied vehicle cream qd for 4 weeks.	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No events met the 5% reporting cutoff in any arm.

Serious adverse events	Roflumilast Cream 0.05%	Vehicle Cream	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 437 (0.23%)	0 / 215 (0.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	0	0	
Skin and subcutaneous tissue disorders			
Cellulitis			
subjects affected / exposed	1 / 437 (0.23%)	0 / 215 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Roflumilast Cream 0.05%	Vehicle Cream	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 437 (0.00%)	0 / 215 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 July 2021	The primary purposes of AM1 were to update Sponsor address.
10 April 2023	The primary purpose of AM2 was to modify the hierarchical order of secondary endpoints.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported