



Clinical trial results:

A Phase IIb, Randomised, Double Blind, Placebo Controlled, Parallel Group, Multicentre Dose Ranging Study of a Subcutaneous Anti-OX40L Monoclonal Antibody (KY1005) in Moderate to Severe Atopic Dermatitis

(Study Testing Response Effect of KY1005 Against Moderate to Severe Atopic Dermatitis. The STREAM-AD Study)

Summary

EudraCT number	2021-000725-28
Trial protocol	ES DE BG HU PL CZ
Global end of trial date	21 February 2024

Results information

Result version number	v1 (current)
This version publication date	30 March 2025
First version publication date	30 March 2025

Trial information

Trial identification

Sponsor protocol code	KY1005-CT05_(DRI17366)
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05131477
WHO universal trial number (UTN)	U1111-1271-1438

Notes:

Sponsors

Sponsor organisation name	Kymab Ltd, a Sanofi Company
Sponsor organisation address	The Eddeva Building (B920), Babraham Research Campus, Cambridge, United Kingdom, CB22 3AT
Public contact	Development Clinical Trial Desk, Kymab Ltd, a Sanofi Company, +44 1223 833301, Contact-us@sanofi.com
Scientific contact	Development Clinical Trial Desk, Kymab Ltd, a Sanofi Company, +44 1223 833301, Contact-us@sanofi.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	15 July 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	21 February 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To characterize the efficacy (including dose/exposure-response) across a range of KY1005 exposures, compared to Placebo, on the signs of Atopic Dermatitis (AD) using the Eczema Area and Severity Index (EASI) in those patients with a documented history, within 6 months prior to Baseline, of either inadequate response to topical treatments or inadvisability of topical treatments.

Protection of trial subjects:

This study was conducted in accordance with the protocol and with the following: consensus ethical principles derived from international guidelines including the Declaration of Helsinki and the applicable amendments, and CIOMS International Ethical Guidelines; applicable ICH GCP guidelines; and applicable laws and regulations.

Participants or their legally authorized representative (if acceptable by local regulations) were required to sign a statement of informed consent that meets the requirements of Title 21 Code of Federal Regulations Part 50, local regulations, ICH guidelines, Health Insurance Portability and Accountability Act requirements, where applicable, and the IRB/IEC or study center.

Background therapy:

The permitted concomitant therapy included treatment with oral contraceptives, nasal, otological, and inhaled corticosteroids for any duration, and oral or topical antibiotics for up to 2 weeks for AD-associated superficial skin infections.

Treatment with the following concomitant medications was prohibited during the study: dupilumab, topical or systemic tacrolimus and pimecrolimus, topical or systemic corticosteroids, leukotriene inhibitors, allergen immunotherapy, systemic treatment with an immunosuppressive/immunomodulating substance, treatment with a live (attenuated) immunisation (immunisation with inactivated seasonal influenza vaccine and inactivated adenovirus COVID-19 vaccines was permitted as per the protocol).

Evidence for comparator:

Placebo

Actual start date of recruitment	13 December 2021
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	4 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 12
Country: Number of subjects enrolled	Canada: 13
Country: Number of subjects enrolled	Japan: 35
Country: Number of subjects enrolled	Taiwan: 17
Country: Number of subjects enrolled	United Kingdom: 4

Country: Number of subjects enrolled	United States: 42
Country: Number of subjects enrolled	Poland: 140
Country: Number of subjects enrolled	Spain: 10
Country: Number of subjects enrolled	Bulgaria: 60
Country: Number of subjects enrolled	Czechia: 34
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Hungary: 8
Worldwide total number of subjects	390
EEA total number of subjects	267

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)	370
From 65 to 84 years	20
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study started in December 2021 and ended in February 2024. An individual participant was part of this study for about 1 year and 5 months. The study took place at 100 sites in 12 countries. Up to 350 participants (approximately 70 participants per treatment group) were planned to be enrolled.

Pre-assignment

Screening details:

The study was performed in 2 parts: Part 1 for all population (baseline to Week 24) for efficacy and safety and Part 2 for Part 1 Responders (Week 24 to Week 52 for efficacy and Week 24 to Week 68 for safety). Responders were defined as participants who achieved \geq EASI 75 and/or IGA 0/1 at Week 24.

Period 1

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

Blinding implementation details:

This was a double-blind study. All participants, the investigators and their study teams, the sponsor, CRO, clinical laboratories were blinded. The IDMC was blinded or unblinded, if needed, to treatment regimen until end of the study (Week 24).

Arms

Are arms mutually exclusive?	Yes
Arm title	250 mg (500 mg LD) KY1005 (Part 1)

Arm description:

Participants randomized to receive 500 mg loading dose of KY1005 at baseline, followed 4 weeks later with 250 mg of KY1005 every 4 weeks (Q4W) injection for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	KY1005
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

500 mg loading dose of KY1005 at baseline (administrated as an injection), followed 4 weeks later with 250 mg of KY1005 every 4 weeks (Q4W) for 24 weeks.

Arm title	250 mg (no LD) KY1005 (Part 1)
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Arm description:

Participants randomized to receive 250 mg (as injection) plus placebo at baseline, followed 4 weeks later with 250 mg Q4W as injection for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	KY1005
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

250 mg of KY1005 (administrated as an injection) at baseline, followed 4 weeks later with 250 mg of KY1005 every 4 weeks (Q4W) for 24 weeks

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

Dosage and administration details:

Matching placebo was administered as an injection at Baseline

Arm title	125 mg KY1005 (Part 1)
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Arm description:

Participants randomized to receive 125 mg (as injection) plus placebo at baseline, followed 4 weeks later with 125 mg Q4W as injection for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	KY1005
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

125 mg of KY1005 (administrated as an injection) at baseline, followed 4 weeks later with 125 mg of KY1005 every 4 weeks (Q4W) for 24 weeks

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

Dosage and administration details:

Matching placebo was administered as an injection at Baseline

Arm title	62.5 mg KY1005 (Part 1)
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Arm description:

Participants randomized to receive 62.5 mg (as injection) plus placebo at baseline, followed 4 weeks later with 62.5 mg Q4W as injection for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	KY1005
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

62.5 mg of KY1005 (administrated as an injection) at baseline, followed 4 weeks later with 62.5 mg of KY1005 every 4 weeks (Q4W) for 24 weeks

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

Dosage and administration details:

Matching placebo was administered as an injection at Baseline

Arm title	Placebo (Part 1)
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Arm description:

Participants randomized to receive placebo given as injections at baseline, followed 4 weeks later with placebo (0 mg) Q4W as injection for 24 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo was administered at Baseline as a subcutaneous injection, followed by an injection every 4 weeks (Q4W) for 24 weeks.

Number of subjects in period 1	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)
Started	77	78	77
Completed Week 24	68	65	69
Re-randomized at Week 24	47 ^[1]	40 ^[2]	45 ^[3]
Randomized and Treated	77	78	77
Completed	68	62	69
Not completed	9	16	8
Consent withdrawn by subject	2	9	6
Physician decision	1	-	-
Adverse event, non-fatal	3	5	1
Other	1	1	-
Randomized and Not Treated	-	-	-
Protocol deviation	2	-	-
Lack of efficacy	-	1	1

Number of subjects in period 1	62.5 mg KY1005 (Part 1)	Placebo (Part 1)
Started	79	79
Completed Week 24	71	60
Re-randomized at Week 24	42 ^[4]	16 ^[5]
Randomized and Treated	78	78
Completed	67	57
Not completed	12	22
Consent withdrawn by subject	2	8
Physician decision	-	-
Adverse event, non-fatal	6	4
Other	-	4
Randomized and Not Treated	1	1
Protocol deviation	1	-
Lack of efficacy	2	5

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants reported in this milestone are shown to clarify the participants flow according to the study design.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants reported in this milestone are shown to clarify the participants flow according to the study design.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants reported in this milestone are shown to clarify the participants flow according to the study design.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants reported in this milestone are shown to clarify the participants flow according to the study design.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants reported in this milestone are shown to clarify the participants flow according to the study design.

Period 2

Period 2 title	Part 2 Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

This was a double-blind study. All participants, the investigators and their study teams, the sponsor, CRO, clinical laboratories were blinded. The IDMC was blinded or unblinded, if needed, to treatment regimen until end of the study (Week 68).

Arms

Are arms mutually exclusive?	Yes
Arm title	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)

Arm description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 250 mg (500 mg LD) at Part 1 and completed Part 1) were re-randomized to receive KY1005 250mg Q4W from Week 24 to Week 52

Arm type	Experimental
Investigational medicinal product name	KY1005
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

250 mg KY1005 were administered every 4 weeks.

Arm title	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)
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Arm description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 250 mg (500 mg LD) at Part 1 and completed Part 1) were re-randomized to receive placebo Q4W from Week 24 to Week 52

Arm type	Placebo
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Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Matching placebo was administered every 4 weeks.

Arm title	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)
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Arm description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 250 mg (no LD) at Part 1 and completed Part 1) were re-randomized to receive KY1005 250mg Q4W from Week 24 to Week 52

Arm type	Experimental
Investigational medicinal product name	KY1005
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

250 mg KY1005 were administered every 4 weeks.

Arm title	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
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Arm description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 250 mg (no LD) at Part 1 and completed Part) 1 were re-randomized to receive placebo Q4W from Week 24 to Week 52

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

Dosage and administration details:

Matching placebo was administered every 4 weeks.

Arm title	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)
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Arm description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 125 mg at Part 1 and completed Part 1) were re-randomized to receive KY1005 125 mg Q4W from Week 24 to Week 52

Arm type	Experimental
Investigational medicinal product name	KY1005
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

125 mg of KY1005 were administered every 4 weeks.

Arm title	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)
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Arm description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 125 mg at Part 1 and completed Part 1) were re-randomized to receive placebo Q4W from Week 24 to Week 52

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Matching placebo was administered every 4 weeks.

Arm title	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)
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Arm description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (62.5 mg) were re-randomized to receive KY1005 62.5mg Q4W from Week 24 to Week 52

Arm type	Experimental
Investigational medicinal product name	KY1005
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

62.5 mg KY1005 were administered every 4 weeks.

Arm title	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
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Arm description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 62.5 mg at Part 1 and completed Part 1) were re-randomized to receive placebo Q4W from Week 24 to Week 52

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Matching placebo was administered every 4 weeks.

Arm title	Placebo (Part 2) Continued From Part 1 Placebo
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Arm description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) placebo received placebo Q4W from Week 24 to Week 52

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

Dosage and administration details:

Matching placebo was administered every 4 weeks.

Number of subjects in period 2^[6]	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)
Started	13	34	12
Re-Randomized and Treated	13	34	11
Completed	12	31	11
Not completed	1	3	1
Consent withdrawn by subject	-	2	-
Other	-	-	-
Re-randomized and Not Treated	-	-	1
Lack of efficacy	1	1	-

Number of subjects in period 2^[6]	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)
Started	28	12	33
Re-Randomized and Treated	28	12	32
Completed	24	11	28
Not completed	4	1	5
Consent withdrawn by subject	-	-	2
Other	1	1	1
Re-randomized and Not Treated	-	-	1
Lack of efficacy	3	-	1

Number of subjects in period 2^[6]	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)	Placebo (Part 2) Continued From Part 1 Placebo
Started	7	35	16
Re-Randomized and Treated	7	34	15
Completed	7	29	13
Not completed	0	6	3
Consent withdrawn by subject	-	2	2
Other	-	1	-
Re-randomized and Not Treated	-	1	1
Lack of efficacy	-	2	-

Notes:

[6] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Part 2 included participants who achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (also named responders at Week 24 and "responder population"). A total of 190 participants were re-randomized 3:1 pre-dose at Week 24 to receive either same pre-Week 24 KY1005 dose/interval or placebo (KY1005 withdrawal group) during Part 2.

Baseline characteristics

Reporting groups

Reporting group title	250 mg (500 mg LD) KY1005 (Part 1)
Reporting group description:	
Participants randomized to receive 500 mg loading dose of KY1005 at baseline, followed 4 weeks later with 250 mg of KY1005 every 4 weeks (Q4W) injection for 24 weeks.	
Reporting group title	250 mg (no LD) KY1005 (Part 1)
Reporting group description:	
Participants randomized to receive 250 mg (as injection) plus placebo at baseline, followed 4 weeks later with 250 mg Q4W as injection for 24 weeks.	
Reporting group title	125 mg KY1005 (Part 1)
Reporting group description:	
Participants randomized to receive 125 mg (as injection) plus placebo at baseline, followed 4 weeks later with 125 mg Q4W as injection for 24 weeks.	
Reporting group title	62.5 mg KY1005 (Part 1)
Reporting group description:	
Participants randomized to receive 62.5 mg (as injection) plus placebo at baseline, followed 4 weeks later with 62.5 mg Q4W as injection for 24 weeks.	
Reporting group title	Placebo (Part 1)
Reporting group description:	
Participants randomized to receive placebo given as injections at baseline, followed 4 weeks later with placebo (0 mg) Q4W as injection for 24 weeks.	

Reporting group values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)
Number of subjects	77	78	77
Age categorical			
Units: Subjects			
Adults (18-64 years)	75	72	72
From 65-84 years	2	6	5
Age continuous			
Units: years			
arithmetic mean	36.3	40.8	37.9
standard deviation	± 13.32	± 15.24	± 15.17
Gender categorical			
Units: Subjects			
Female	30	35	39
Male	47	43	38
Race			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	12	12	10
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	2	4
White	61	63	63
More than one race	0	0	0
Unknown or Not Reported	0	1	0

EASI Score at Baseline			
Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition.			
Units: units on a scale			
arithmetic mean	30.3	28.7	30.3
standard deviation	± 11.66	± 10.53	± 12.43

Reporting group values	62.5 mg KY1005 (Part 1)	Placebo (Part 1)	Total
Number of subjects	79	79	390
Age categorical			
Units: Subjects			
Adults (18-64 years)	74	77	370
From 65-84 years	5	2	20
Age continuous			
Units: years			
arithmetic mean	37.6	36.4	-
standard deviation	± 14.78	± 13.07	-
Gender categorical			
Units: Subjects			
Female	37	30	171
Male	42	49	219
Race			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	14	12	60
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	6	20
White	60	60	307
More than one race	0	0	0
Unknown or Not Reported	1	1	3

EASI Score at Baseline			
Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition.			
Units: units on a scale			
arithmetic mean	28.7	26.4	-
standard deviation	± 10.09	± 7.85	-

End points

End points reporting groups

Reporting group title	250 mg (500 mg LD) KY1005 (Part 1)
Reporting group description: Participants randomized to receive 500 mg loading dose of KY1005 at baseline, followed 4 weeks later with 250 mg of KY1005 every 4 weeks (Q4W) injection for 24 weeks.	
Reporting group title	250 mg (no LD) KY1005 (Part 1)
Reporting group description: Participants randomized to receive 250 mg (as injection) plus placebo at baseline, followed 4 weeks later with 250 mg Q4W as injection for 24 weeks.	
Reporting group title	125 mg KY1005 (Part 1)
Reporting group description: Participants randomized to receive 125 mg (as injection) plus placebo at baseline, followed 4 weeks later with 125 mg Q4W as injection for 24 weeks.	
Reporting group title	62.5 mg KY1005 (Part 1)
Reporting group description: Participants randomized to receive 62.5 mg (as injection) plus placebo at baseline, followed 4 weeks later with 62.5 mg Q4W as injection for 24 weeks.	
Reporting group title	Placebo (Part 1)
Reporting group description: Participants randomized to receive placebo given as injections at baseline, followed 4 weeks later with placebo (0 mg) Q4W as injection for 24 weeks.	
Reporting group title	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)
Reporting group description: Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 250 mg (500 mg LD) at Part 1 and completed Part 1) were re-randomized to receive KY1005 250mg Q4W from Week 24 to Week 52	
Reporting group title	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)
Reporting group description: Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 250 mg (500 mg LD) at Part 1 and completed Part 1) were re-randomized to receive placebo Q4W from Week 24 to Week 52	
Reporting group title	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)
Reporting group description: Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 250 mg (no LD) at Part 1 and completed Part 1) were re-randomized to receive KY1005 250mg Q4W from Week 24 to Week 52	
Reporting group title	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Reporting group description: Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 250 mg (no LD) at Part 1 and completed Part) 1 were re-randomized to receive placebo Q4W from Week 24 to Week 52	
Reporting group title	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)
Reporting group description: Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 125 mg at Part 1 and completed Part 1) were re-randomized to receive KY1005 125 mg Q4W from Week 24 to Week 52	
Reporting group title	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)
Reporting group description: Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 125 mg at Part 1 and completed Part 1) were re-randomized to receive placebo Q4W from Week 24 to Week 52	
Reporting group title	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)

Reporting group description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (62.5 mg) were re-randomized to receive KY1005 62.5mg Q4W from Week 24 to Week 52

Reporting group title	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
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Reporting group description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) (who received 62.5 mg at Part 1 and completed Part 1) were re-randomized to receive placebo Q4W from Week 24 to Week 52

Reporting group title	Placebo (Part 2) Continued From Part 1 Placebo
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Reporting group description:

Participants who completed Part 1 and who were responders (achieved \geq EASI 75 and/or who attained IGA 0/1 at Week 24 (Day 169) placebo received placebo Q4W from Week 24 to Week 52

Primary: Percentage Change in EASI (Eczema Area and Severity Index) From Baseline to Week 16 (Part 1)

End point title	Percentage Change in EASI (Eczema Area and Severity Index) From Baseline to Week 16 (Part 1)
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End point description:

Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. Full Analysis Set for Part 1. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Efficacy analyses were based on treatment allocated at randomization. The Primary efficacy endpoint is the percentage of change in EASI from Baseline to Day 113 (Week 16). The primary analysis was conducted on FAS1 after all the randomized patients have reached the Day 169 (Week 24) visit/ early termination.

End point type	Primary
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End point timeframe:

Baseline to Week 16

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of change				
least squares mean (standard error)				
Percentage Change in EASI from baseline to Week 16	-61.5 (\pm 4.68)	-56.8 (\pm 4.59)	-51.6 (\pm 4.59)	-59.6 (\pm 4.53)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of change				
least squares mean (standard error)				
Percentage Change in EASI from baseline to Week 16	-29.4 (\pm 4.76)			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	250 mg (500 mg LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-32.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.9
upper limit	-20.3
Variability estimate	Standard error of the mean
Dispersion value	6.01

Statistical analysis title	Statistical analysis 2
Comparison groups	250 mg (no LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-27.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.1
upper limit	-15.6
Variability estimate	Standard error of the mean
Dispersion value	5.98

Statistical analysis title	Statistical analysis 3
Comparison groups	125 mg KY1005 (Part 1) v Placebo (Part 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-22.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34
upper limit	-10.4
Variability estimate	Standard error of the mean
Dispersion value	6.01

Statistical analysis title	Statistical analysis 4
Comparison groups	62.5 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-30.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.9
upper limit	-18.5
Variability estimate	Standard error of the mean
Dispersion value	5.95

Secondary: Percentage Change in EASI (Eczema Area and Severity Index) From Baseline to Week 24 (Part 1)

End point title	Percentage Change in EASI (Eczema Area and Severity Index) From Baseline to Week 24 (Part 1)
End point description:	
Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. The primary analysis was conducted on the FAS1 after all randomized patients have reached day 169 (Week 24) visit/ early termination. Percentage change from baseline in EASI at Day 169 (Week 24).	
End point type	Secondary
End point timeframe:	
Baseline to Week 24	

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of change				
least squares mean (standard error)				
Percent Change in EASI At Day 169 (Week 24)	-64.4 (± 5.17)	-52.2 (± 5.14)	-53.7 (± 5.08)	-54.4 (± 5.09)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of change				
least squares mean (standard error)				
Percent Change in EASI At Day 169 (Week 24)	-27.6 (± 5.29)			

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	250 mg (500 mg LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-36.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-49.8
upper limit	-23.8
Variability estimate	Standard error of the mean
Dispersion value	6.62

Statistical analysis title	Statistical analysis 2
Comparison groups	250 mg (no LD) KY1005 (Part 1) v Placebo (Part 1)

Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-24.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.7
upper limit	-11.6
Variability estimate	Standard error of the mean
Dispersion value	6.67

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo (Part 1) v 125 mg KY1005 (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-26.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.2
upper limit	-13.1
Variability estimate	Standard error of the mean
Dispersion value	6.65

Statistical analysis title	Statistical analysis 4
Comparison groups	62.5 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-26.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.7
upper limit	-13.9

Variability estimate	Standard error of the mean
Dispersion value	6.58

Secondary: Percentage of Participants With at Least a 75% Reduction From Baseline in EASI (EASI 75) at Week 16 and Week 24 (Part 1)

End point title	Percentage of Participants With at Least a 75% Reduction From Baseline in EASI (EASI 75) at Week 16 and Week 24 (Part 1)
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End point description:

Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. The primary analysis was conducted on the FAS1 after all randomized patients have reached day 169 (Week 24) visit/ early termination. Percentage of patients with at least 75% reduction from baseline in EASI (EASI 75) at days 113 (Week 16) and Day 169 (Week 24).

End point type	Secondary
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End point timeframe:

Baseline to Week 16 and Week 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of participants				
number (not applicable)				
Week 16	40.3	38.5	42.9	40.5
Week 24	54.5	38.5	49.4	40.5

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of participants				
number (not applicable)				
Week 16	11.4			
Week 24	17.7			

Statistical analyses

Statistical analysis title	Statistical analysis 1 - Week 16
Comparison groups	250 mg (500 mg LD) KY1005 (Part 1) v Placebo (Part 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	0.42

Statistical analysis title	Statistical analysis 2 - Week 16
Comparison groups	250 mg (no LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.14
upper limit	0.4

Statistical analysis title	Statistical analysis 3 - Week 16
Comparison groups	125 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	0.44

Statistical analysis title	Statistical analysis 4 - Week 16
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Comparison groups	62.5 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	0.42

Statistical analysis title	Statistical analysis 1 - Week 24
Comparison groups	250 mg (500 mg LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.23
upper limit	0.5

Statistical analysis title	Statistical analysis 2 - Week 24
Comparison groups	250 mg (no LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.07
upper limit	0.34

Statistical analysis title	Statistical analysis 3 - Week 24
Comparison groups	125 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Confidence interval	
level	95 %

Statistical analysis title	Statistical analysis 4 - Week 24
Comparison groups	62.5 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0016
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	0.36

Secondary: Percentage of Participants With a Response of IGA (Investigator Global Assessment) 0 or 1 and a Reduction From Baseline \geq 2 Points (Part 1)

End point title	Percentage of Participants With a Response of IGA (Investigator Global Assessment) 0 or 1 and a Reduction From Baseline \geq 2 Points (Part 1)
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End point description:

The IGA is a five-point scale that provides a global clinical assessment of AD severity ranging from 0 to 4, where 0 indicates clear, 2 is mild, 3 is moderate, and 4 indicates severe AD.

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. The primary analysis was conducted on the FAS1 after all randomized patients have reached day 169 (Week 24) visit/early termination. Percentage of patients with a response of IGA 0 or 1 and a reduction from baseline of \geq 2 points at Days 113 (Week 16) and Day 169 (Week 24).

End point type	Secondary
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End point timeframe:

Baseline to Week 16 and Week 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of participants				
number (not applicable)				
Week 16	22.1	14.1	19.5	25.3
Week 24	45.5	33.3	40.3	29.1

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of participants				
number (not applicable)				
Week 16	5.1			
Week 24	11.4			

Statistical analyses

Statistical analysis title	Statistical analysis 1 - Week 16
Comparison groups	250 mg (500 mg LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0022
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	0.27

Statistical analysis title	Statistical analysis 2 - Week 16
Comparison groups	250 mg (no LD) KY1005 (Part 1) v Placebo (Part 1)

Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0562
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.18

Statistical analysis title	Statistical analysis 3 - Week 16
Comparison groups	125 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0054
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.24

Statistical analysis title	Statistical analysis 4 - Week 16
Comparison groups	62.5 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.31

Statistical analysis title	Statistical analysis 1 - Week 24
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Comparison groups	250 mg (500 mg LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.21
upper limit	0.47

Statistical analysis title	Statistical analysis 2 - Week 24
Comparison groups	250 mg (no LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0008
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	0.34

Statistical analysis title	Statistical analysis 3 - Week 24
Comparison groups	125 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	0.41

Statistical analysis title	Statistical analysis 4 -Week 24
Comparison groups	Placebo (Part 1) v 62.5 mg KY1005 (Part 1)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0046
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	0.3

Secondary: Percentage of Participants With Improvement (Reduction) of Weekly Average of Pruritus NRS (Numerical Rating Scale) \geq 4 With a Baseline Pruritus of \geq 4 From Baseline (Part 1)

End point title	Percentage of Participants With Improvement (Reduction) of Weekly Average of Pruritus NRS (Numerical Rating Scale) \geq 4 With a Baseline Pruritus of \geq 4 From Baseline (Part 1)
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End point description:

The pruritus NRS is a simple assessment tool to report the intensity of their pruritus (itch) ranges from 0 to 10 with 0 being "no itch" and 10 being the "worst itch imaginable".

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. The primary analysis was conducted on the FAS1 after all randomized patients have reached day 169 (Week 24) visit/ early termination. Proportion of patients with improvement (reduction) of weekly average of pruritus NRS \geq 4 a baseline pruritis NRS of \geq 4 from baseline to Days 113 (Week 16) and Day 169 (Week 24).

End point type	Secondary
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End point timeframe:

Baseline to Week 16 and Week 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of participants				
number (not applicable)				
Week 16	24.7	19.2	20.8	22.8
Week 24	31.2	24.4	28.6	27.8

End point values	Placebo (Part 1)			
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Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of participants				
number (not applicable)				
Week 16	5.1			
Week 24	7.6			

Statistical analyses

Statistical analysis title	Statistical analysis 1 - Week 16
Comparison groups	250 mg (500 mg LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	0.3

Statistical analysis title	Statistical analysis 2 - Week 16
Comparison groups	250 mg (no LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0057
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.24

Statistical analysis title	Statistical analysis 3 - Week 16
Comparison groups	125 mg KY1005 (Part 1) v Placebo (Part 1)

Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0038
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.05
upper limit	0.26

Statistical analysis title	Statistical analysis 4 - Week 16
Comparison groups	62.5 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0011
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.07
upper limit	0.28

Statistical analysis title	Statistical analysis 1 - Week 24
Comparison groups	250 mg (500 mg LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.11
upper limit	0.35

Statistical analysis title	Statistical analysis 2 - Week 24
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Comparison groups	250 mg (no LD) KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0038
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	0.28

Statistical analysis title	Statistical analysis 3 - Week 24
Comparison groups	125 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	0.32

Statistical analysis title	Statistical analysis 4 - Week 24
Comparison groups	62.5 mg KY1005 (Part 1) v Placebo (Part 1)
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0008
Method	Cochran-Mantel-Haenszel
Parameter estimate	Proportion difference
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	0.32

Secondary: Absolute Change From Baseline in EASI (Eczema Area and Severity Index) (Part 1)

End point title	Absolute Change From Baseline in EASI (Eczema Area and Severity Index) (Part 1)
End point description:	
Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.	
End point type	Secondary
End point timeframe:	
Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24	

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 2 (N=73, 77, 75, 75, 78)	-8.49 (± 10.777)	-5.27 (± 8.485)	-6.17 (± 10.071)	-7.51 (± 8.836)
Week 4 (N= 76, 74, 76, 77, 75)	-11.21 (± 10.612)	-8.38 (± 9.944)	-10.33 (± 10.861)	-10.27 (± 10.550)
Week 8 (N= 70, 70, 75, 76, 72)	-15.67 (± 11.872)	-11.93 (± 11.018)	-13.77 (± 12.964)	-14.37 (± 10.054)
Week 12 (N= 70, 70, 72, 77, 70)	-18.49 (± 12.411)	-13.84 (± 11.121)	-16.56 (± 14.062)	-16.46 (± 11.699)
Week 16 (N= 70, 69, 73, 76, 69)	-19.71 (± 12.731)	-16.31 (± 12.329)	-15.70 (± 14.226)	-17.82 (± 11.730)
Week 20 (N= 67, 69, 72, 72, 67)	-21.93 (± 14.283)	-16.46 (± 12.834)	-16.98 (± 15.321)	-16.76 (± 12.590)
Week 24 (N= 71, 68, 72, 70, 67)	-21.92 (± 14.475)	-15.72 (± 12.977)	-16.91 (± 15.085)	-17.09 (± 13.088)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 2 (N=73, 77, 75, 75, 78)	-3.98 (± 7.855)			
Week 4 (N= 76, 74, 76, 77, 75)	-7.20 (± 8.510)			
Week 8 (N= 70, 70, 75, 76, 72)	-7.64 (± 10.450)			
Week 12 (N= 70, 70, 72, 77, 70)	-8.76 (± 9.608)			
Week 16 (N= 70, 69, 73, 76, 69)	-7.47 (± 11.338)			

Week 20 (N= 67, 69, 72, 72, 67)	-7.91 (± 11.163)			
Week 24 (N= 71, 68, 72, 70, 67)	-7.52 (± 12.537)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in EASI (Eczema Area and Severity Index) (Part 1)

End point title	Percentage Change From Baseline in EASI (Eczema Area and Severity Index) (Part 1)
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End point description:

Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percent of change				
arithmetic mean (standard deviation)				
Week 2 (N= 73, 77, 75, 75, 78)	-27.94 (± 30.032)	-17.75 (± 38.988)	-19.09 (± 39.499)	-26.03 (± 34.462)
Week 4 (N= 76, 74, 76, 77, 75)	-36.85 (± 28.901)	-29.13 (± 42.013)	-35.10 (± 34.457)	-35.49 (± 38.786)
Week 8 (N= 70, 70, 75, 76, 72)	-50.25 (± 30.666)	-41.21 (± 41.129)	-45.96 (± 38.150)	-51.70 (± 31.046)
Week 12 (N= 70, 70, 72, 77, 70)	-59.61 (± 30.717)	-50.15 (± 36.086)	-55.23 (± 40.218)	-57.36 (± 34.275)
Week 16 (N= 70, 69, 73, 76, 69)	-62.35 (± 32.322)	-59.98 (± 37.444)	-52.50 (± 40.820)	-61.51 (± 31.663)
Week 20 (N= 67, 69, 72, 72, 67)	-67.85 (± 33.135)	-57.80 (± 38.921)	-56.29 (± 43.103)	-57.87 (± 38.977)
Week 24 (N= 71, 68, 72, 70, 67)	-68.01 (± 36.052)	-55.84 (± 40.299)	-56.72 (± 44.271)	-57.37 (± 40.225)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			

Units: percent of change				
arithmetic mean (standard deviation)				
Week 2 (N= 73, 77, 75, 75, 78)	-15.26 (± 34.143)			
Week 4 (N= 76, 74, 76, 77, 75)	-27.56 (± 31.037)			
Week 8 (N= 70, 70, 75, 76, 72)	-28.70 (± 38.603)			
Week 12 (N= 70, 70, 72, 77, 70)	-33.72 (± 35.358)			
Week 16 (N= 70, 69, 73, 76, 69)	-28.25 (± 41.173)			
Week 20 (N= 67, 69, 72, 72, 67)	-30.32 (± 40.486)			
Week 24 (N= 71, 68, 72, 70, 67)	-28.55 (± 44.004)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With at Least a 50% Reduction From Baseline in EASI (EASI 50) (Part 1)

End point title	Percentage of Participants With at Least a 50% Reduction From Baseline in EASI (EASI 50) (Part 1)
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End point description:

Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of participants				
number (not applicable)				
Week 2	19.5	15.4	16.9	22.8
Week 4	29.9	21.8	39.0	39.2
Week 8	45.5	38.5	53.2	54.4
Week 12	62.3	44.9	61.0	62.0
Week 16	63.6	52.6	57.1	65.8
Week 20	63.6	51.3	58.4	58.2
Week 24	66.2	43.6	55.8	53.2

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of participants				
number (not applicable)				
Week 2	13.9			
Week 4	24.1			
Week 8	27.8			
Week 12	26.6			
Week 16	27.8			
Week 20	25.3			
Week 24	24.1			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With at Least a 75% Reduction From Baseline in EASI (EASI 75) (Part 1)

End point title	Percentage of Participants With at Least a 75% Reduction From Baseline in EASI (EASI 75) (Part 1)
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End point description:

Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of participants				
number (not applicable)				
Week 2	9.1	2.6	2.6	2.5
Week 4	9.1	9.0	11.7	11.4
Week 8	23.4	16.7	27.3	25.3
Week 12	33.8	25.6	44.2	43.0
Week 16	40.3	38.5	42.9	40.5
Week 20	49.4	42.3	48.1	40.5
Week 24	54.5	38.5	49.4	40.5

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of participants				
number (not applicable)				
Week 2	5.1			
Week 4	6.3			
Week 8	8.9			
Week 12	11.4			
Week 16	11.4			
Week 20	13.9			
Week 24	17.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With at Least a 90% Reduction From Baseline in EASI (EASI 90) (Part 1)

End point title	Percentage of Participants With at Least a 90% Reduction From Baseline in EASI (EASI 90) (Part 1)
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End point description:

Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percent				
number (not applicable)				
Week 2	2.6	1.3	0	1.3
Week 4	6.5	1.3	1.3	2.5
Week 8	7.8	7.7	9.1	8.9
Week 12	10.4	9.0	14.3	12.7
Week 16	15.6	14.1	16.9	19.0
Week 20	27.3	23.1	24.7	19.0
Week 24	37.7	26.9	32.5	24.1

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percent				
number (not applicable)				
Week 2	0			
Week 4	0			
Week 8	1.3			
Week 12	5.1			
Week 16	3.8			
Week 20	7.6			
Week 24	11.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a 100% Reduction From Baseline in EASI (EASI 100) (Part 1)

End point title	Percentage of Participants With a 100% Reduction From Baseline in EASI (EASI 100) (Part 1)
End point description:	Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24.
End point type	Secondary
End point timeframe:	Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of participants				
number (not applicable)				
Week 2	0	1.3	0	0
Week 4	2.6	0	0	0
Week 8	2.6	5.1	1.3	0
Week 12	3.9	2.6	2.6	2.5
Week 16	3.9	1.3	2.6	1.3
Week 20	6.5	6.4	3.9	2.5
Week 24	7.8	6.4	9.1	1.3

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of participants				
number (not applicable)				
Week 2	0			
Week 4	0			
Week 8	0			
Week 12	0			
Week 16	1.3			
Week 20	1.3			
Week 24	3.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in IGA (Investigator Global Assessment) From Baseline to Week 24 (Part 1)

End point title	Change in IGA (Investigator Global Assessment) From Baseline to Week 24 (Part 1)
End point description:	<p>The IGA is a five-point scale that provides a global clinical assessment of AD severity ranging from 0 to 4, where 0 indicates clear, 2 is mild, 3 is moderate, and 4 indicates severe AD.</p> <p>The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.</p>
End point type	Secondary
End point timeframe:	Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: score on scale				
arithmetic mean (standard deviation)				
Week 2 (N= 73, 77, 75, 75, 78)	-0.33 (± 0.625)	-0.21 (± 0.408)	-0.29 (± 0.540)	-0.23 (± 0.481)
Week 4 (N= 76, 74, 76, 77, 75)	-0.57 (± 0.869)	-0.38 (± 0.590)	-0.45 (± 0.620)	-0.51 (± 0.661)
Week 8 (N= 70, 70, 75, 76, 72)	-0.79 (± 0.976)	-0.74 (± 0.829)	-0.80 (± 0.900)	-0.76 (± 0.709)
Week 12 (N= 70, 70, 72, 77, 70)	-1.10 (± 1.024)	-0.87 (± 0.867)	-1.04 (± 1.013)	-1.00 (± 0.973)

Week 16 (N= 70, 69, 73, 76, 69)	-1.23 (± 0.981)	-0.99 (± 0.899)	-0.96 (± 1.033)	-1.09 (± 0.969)
Week 20 (N= 67, 69, 72, 72, 67)	-1.43 (± 1.118)	-1.17 (± 1.137)	-1.11 (± 1.120)	-1.10 (± 0.981)
Week 24 (N= 71, 68, 72, 70, 67)	-1.48 (± 1.205)	-1.16 (± 1.241)	-1.32 (± 1.265)	-1.16 (± 1.030)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: score on scale				
arithmetic mean (standard deviation)				
Week 2 (N= 73, 77, 75, 75, 78)	-0.18 (± 0.503)			
Week 4 (N= 76, 74, 76, 77, 75)	-0.31 (± 0.592)			
Week 8 (N= 70, 70, 75, 76, 72)	-0.32 (± 0.728)			
Week 12 (N= 70, 70, 72, 77, 70)	-0.36 (± 0.660)			
Week 16 (N= 70, 69, 73, 76, 69)	-0.43 (± 0.757)			
Week 20 (N= 67, 69, 72, 72, 67)	-0.45 (± 0.822)			
Week 24 (N= 71, 68, 72, 70, 67)	-0.49 (± 0.959)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in IGA (Investigator Global Assessment) From Baseline (Part 2)

End point title	Change in IGA (Investigator Global Assessment) From Baseline (Part 2)
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End point description:

The IGA is a five-point scale that provides a global clinical assessment of AD severity ranging from 0 to 4, where 0 indicates clear, 2 is mild, 3 is moderate, and 4 indicates severe AD.

The Full Analysis Set (FAS2) for Part 2 included all re-randomized at week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 28, 31, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28 12, 33, 5, 33, 16)	-2.31 (± 0.855)	-1.91 (± 1.026)	-2.00 (± 0.953)	-1.82 (± 1.156)
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 14)	-2.46 (± 0.967)	-2.00 (± 1.155)	-2.17 (± 1.193)	-1.46 (± 1.138)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-2.00 (± 1.000)	-1.82 (± 1.314)	-1.73 (± 1.348)	-1.32 (± 1.188)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-2.08 (± 1.188)	-1.70 (± 1.380)	-1.40 (± 1.174)	-1.29 (± 1.182)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-2.08 (± 1.115)	-1.71 (± 1.395)	-1.64 (± 1.286)	-1.29 (± 1.301)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-2.00 (± 1.155)	-1.69 (± 1.447)	-1.73 (± 1.348)	-1.32 (± 1.335)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-1.69 (± 1.182)	-1.69 (± 1.469)	-1.60 (± 1.350)	-1.36 (± 1.367)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 31, 14)	-1.77 (± 1.301)	-1.55 (± 1.434)	-1.64 (± 1.286)	-1.36 (± 1.420)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28 12, 33, 5, 33, 16)	-2.42 (± 0.793)	-1.82 (± 1.131)	-2.00 (± 1.000)	-1.73 (± 0.911)
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 14)	-2.25 (± 0.965)	-1.74 (± 1.064)	-1.71 (± 0.951)	-1.47 (± 0.961)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-2.33 (± 0.985)	-1.75 (± 1.078)	-1.71 (± 0.951)	-1.41 (± 1.160)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-2.17 (± 1.115)	-1.81 (± 1.230)	-2.00 (± 1.000)	-1.53 (± 1.344)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-2.36 (± 1.120)	-1.75 (± 1.164)	-1.86 (± 1.215)	-1.58 (± 1.311)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-2.08 (± 1.084)	-1.63 (± 1.070)	-1.71 (± 1.113)	-1.58 (± 1.259)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-2.08 (± 1.084)	-1.50 (± 1.137)	-2.00 (± 1.414)	-1.63 (± 1.351)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 31, 14)	-2.18 (± 1.401)	-1.48 (± 1.214)	-2.00 (± 1.155)	-1.65 (± 1.305)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28 12, 33, 5, 33, 16)	-1.63 (± 1.204)			
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 14)	-1.71 (± 1.383)			
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-1.67 (± 1.234)			
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-1.67 (± 1.234)			
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-1.53 (± 1.302)			
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-1.64 (± 1.393)			
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-1.71 (± 1.590)			
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 31, 14)	-1.79 (± 1.672)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With a Score of IGA (Investigator Global Assessment) 0 or 1 and a Reduction From Baseline of ≥ 2 Points (Part 1)

End point title	Percentage of Participants With a Score of IGA (Investigator Global Assessment) 0 or 1 and a Reduction From Baseline of ≥ 2 Points (Part 1)
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End point description:

The IGA is a five-point scale that provides a global clinical assessment of AD (Atopic Dermatitis) severity ranging from 0 to 4, where 0 indicates clear, 2 is mild, 3 is moderate, and 4 indicates severe AD. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of participants				
number (not applicable)				
Week 2	1.3	0	0	0
Week 4	5.2	1.3	1.3	2.5

Week 8	9.1	9.0	13.0	5.1
Week 12	16.9	12.8	19.5	19.0
Week 16	22.1	14.1	19.5	25.3
Week 20	33.8	25.6	27.3	21.5
Week 24	45.5	33.3	40.3	29.1

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of participants				
number (not applicable)				
Week 2	1.3			
Week 4	2.5			
Week 8	5.1			
Week 12	3.8			
Week 16	5.1			
Week 20	8.9			
Week 24	11.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in SCORAD (SCORing Atopic Dermatitis) Index From Baseline (Part 1)

End point title	Absolute Change in SCORAD (SCORing Atopic Dermatitis) Index From Baseline (Part 1)
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End point description:

SCORAD was used to assess the extent and severity of AD (Atopic Dermatitis). Extent and severity of eczema as well as subjective assessment of symptoms were assessed and scored. SCORAD total score ranges from 0 (absent disease) to 103 (severe disease).

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: score on a scale				
arithmetic mean (standard deviation)				

Week 4 (N= 76, 74, 76, 77, 75)	-15.30 (± 16.517)	-12.27 (± 13.455)	-15.89 (± 14.865)	-14.43 (± 13.691)
Week 8 (N= 70, 70, 75, 76, 72)	-22.39 (± 19.368)	-19.61 (± 17.527)	-21.49 (± 19.200)	-21.42 (± 16.956)
Week 12 (N= 70, 70, 72, 77, 70)	-27.80 (± 19.621)	-22.31 (± 17.936)	-27.72 (± 20.084)	-26.45 (± 19.649)
Week 16 (N= 70, 69, 73, 76, 68)	-30.12 (± 20.086)	-25.07 (± 20.233)	-26.28 (± 21.258)	-28.15 (± 19.831)
Week 20 (N= 67, 69, 72, 72, 67)	-34.89 (± 22.369)	-28.04 (± 22.472)	-29.80 (± 23.594)	-26.71 (± 21.056)
Week 24 (N= 71, 68, 70, 70, 67)	-36.19 (± 24.605)	-27.28 (± 22.937)	-29.96 (± 25.735)	-28.48 (± 21.793)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N= 76, 74, 76, 77, 75)	-11.13 (± 14.243)			
Week 8 (N= 70, 70, 75, 76, 72)	-12.50 (± 16.584)			
Week 12 (N= 70, 70, 72, 77, 70)	-13.97 (± 16.898)			
Week 16 (N= 70, 69, 73, 76, 68)	-13.85 (± 18.123)			
Week 20 (N= 67, 69, 72, 72, 67)	-13.91 (± 19.325)			
Week 24 (N= 71, 68, 70, 70, 67)	-15.08 (± 22.739)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in SCORAD (SCORing Atopic Dermatitis) Index From Baseline (Part 2)

End point title	Absolute Change in SCORAD (SCORing Atopic Dermatitis) Index From Baseline (Part 2)
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End point description:

SCORAD was used to assess the extent and severity of AD (Atopic Dermatitis). Extent and severity of eczema as well as subjective assessment of symptoms were assessed and scored. SCORAD total score ranges from 0 (absent disease) to 103 (severe disease).

The Full Analysis Set (FAS2) for Part 2 included all re-randomized participants at Week 24.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 31, 5, 33, 16)	-52.22 (± 14.314)	-44.25 (± 21.879)	-42.44 (± 21.879)	-36.77 (± 21.919)
Week 28 (N= 13, 34, 12, 28, 12, 31, 7, 34, 13)	-54.19 (± 18.525)	-44.30 (± 23.737)	-43.38 (± 24.261)	-33.40 (± 23.845)
Week 32 (N= 13, 34, 11, 28, 12, 32, 7, 32, 15)	-51.19 (± 23.086)	-41.55 (± 25.962)	-37.58 (± 27.000)	-28.31 (± 23.318)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-49.68 (± 25.709)	-38.72 (± 27.164)	-33.91 (± 26.686)	-27.91 (± 24.154)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-49.88 (± 26.342)	-38.96 (± 29.090)	-36.05 (± 27.550)	-30.05 (± 26.602)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-47.38 (± 26.194)	-38.61 (± 28.602)	-37.95 (± 28.362)	-29.98 (± 26.387)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-39.75 (± 25.447)	-38.18 (± 29.948)	-35.13 (± 27.409)	-29.71 (± 28.021)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-40.26 (± 26.751)	-34.69 (± 28.925)	-35.04 (± 27.120)	-29.26 (± 27.488)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 31, 5, 33, 16)	-49.87 (± 13.012)	-41.65 (± 24.173)	-45.20 (± 18.017)	-38.45 (± 22.077)
Week 28 (N= 13, 34, 12, 28, 12, 31, 7, 34, 13)	-47.15 (± 16.401)	-43.95 (± 24.475)	-41.17 (± 19.190)	-37.46 (± 23.843)
Week 32 (N= 13, 34, 11, 28, 12, 32, 7, 32, 15)	-50.76 (± 16.285)	-44.04 (± 22.541)	-40.76 (± 17.685)	-36.72 (± 25.421)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-52.12 (± 19.167)	-45.28 (± 23.438)	-40.09 (± 16.767)	-37.15 (± 27.483)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-52.42 (± 19.560)	-42.93 (± 24.694)	-45.31 (± 22.710)	-37.75 (± 27.127)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-51.14 (± 20.299)	-40.96 (± 24.470)	-36.39 (± 21.651)	-36.83 (± 27.061)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-52.40 (± 22.250)	-38.38 (± 24.940)	-43.80 (± 27.380)	-37.64 (± 28.543)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-50.26 (± 26.772)	-37.07 (± 25.763)	-42.26 (± 25.861)	-38.41 (± 26.915)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 31, 5, 33, 16)	-40.54 (± 23.584)			
Week 28 (N= 13, 34, 12, 28, 12, 31, 7, 34, 13)	-42.98 (± 24.770)			
Week 32 (N= 13, 34, 11, 28, 12, 32, 7, 32, 15)	-37.81 (± 25.964)			
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-39.35 (± 25.340)			
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-36.74 (± 25.865)			
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-37.47 (± 27.887)			
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-38.10 (± 28.181)			
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-39.94 (± 29.182)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in SCORAD (SCORing Atopic Dermatitis) Index From Baseline (Part 1)

End point title	Percentage Change in SCORAD (SCORing Atopic Dermatitis) Index From Baseline (Part 1)
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End point description:

SCORAD was used to assess the extent and severity of AD (Atopic Dermatitis). Extent and severity of eczema as well as subjective assessment of symptoms were assessed and scored. SCORAD total score ranges from 0 (absent disease) to 103 (severe disease).

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 4 (N= 76, 74, 76, 77, 75)	-22.02 (± 22.050)	-18.52 (± 20.315)	-22.76 (± 20.903)	-21.42 (± 21.101)

Week 8 (N= 70, 70, 75, 76, 72)	-31.84 (± 24.549)	-30.00 (± 28.050)	-30.47 (± 26.260)	-32.07 (± 23.600)
Week 12 (N= 70, 70, 72, 77, 70)	-40.32 (± 25.145)	-33.64 (± 26.502)	-39.38 (± 27.228)	-39.22 (± 26.807)
Week 16 (N= 70, 69, 73, 76, 68)	-43.25 (± 26.555)	-37.18 (± 28.395)	-37.33 (± 29.071)	-41.44 (± 26.134)
Week 20 (N= 67, 69, 72, 72, 67)	-49.92 (± 28.279)	-42.07 (± 32.179)	-42.30 (± 32.422)	-39.05 (± 28.347)
Week 24 (N= 71, 68, 70, 70, 67)	-57.87 (± 32.609)	-41.04 (± 34.212)	-42.58 (± 35.812)	-41.49 (± 29.263)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 4 (N= 76, 74, 76, 77, 75)	-16.67 (± 21.045)			
Week 8 (N= 70, 70, 75, 76, 72)	-18.27 (± 23.875)			
Week 12 (N= 70, 70, 72, 77, 70)	-20.70 (± 24.587)			
Week 16 (N= 70, 69, 73, 76, 68)	-20.87 (± 26.791)			
Week 20 (N= 67, 69, 72, 72, 67)	-20.88 (± 28.527)			
Week 24 (N= 71, 68, 70, 70, 67)	-22.21 (± 33.233)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in SCORAD (SCORing Atopic Dermatitis) Index From Baseline (Part 2)

End point title	Percentage Change in SCORAD (SCORing Atopic Dermatitis) Index From Baseline (Part 2)
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End point description:

SCORAD was used to assess the extent and severity of AD (Atopic Dermatitis). Extent and severity of eczema as well as subjective assessment of symptoms were assessed and scored. SCORAD total score ranges from 0 (absent disease) to 103 (severe disease).

The Full Analysis Set (FAS2) for Part 2 included all re-randomized at Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 31, 5, 33, 16)	-76.47 (± 11.581)	-63.86 (± 27.005)	-60.09 (± 26.373)	-57.73 (± 34.302)
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 13)	-78.39 (± 16.236)	-63.35 (± 28.625)	-62.58 (± 32.229)	-52.12 (± 35.950)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-72.44 (± 25.786)	-59.37 (± 33.889)	-53.42 (± 34.955)	-44.49 (± 35.890)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-71.50 (± 31.364)	-55.13 (± 35.598)	-49.88 (± 36.111)	-43.78 (± 36.278)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-71.43 (± 31.643)	-54.79 (± 38.533)	-51.85 (± 37.053)	-46.81 (± 39.055)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-67.26 (± 31.749)	-54.96 (± 38.272)	-54.10 (± 37.251)	-46.95 (± 39.736)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-59.99 (± 35.979)	-53.71 (± 39.548)	-51.66 (± 37.347)	-45.48 (± 41.426)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-60.41 (± 36.686)	-49.90 (± 40.104)	-49.68 (± 35.129)	-44.93 (± 40.527)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 31, 5, 33, 16)	-72.55 (± 15.422)	-58.96 (± 31.260)	-66.12 (± 19.532)	-55.75 (± 26.945)
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 13)	-68.39 (± 21.143)	-61.69 (± 32.214)	-64.22 (± 18.649)	-53.98 (± 29.707)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-74.03 (± 21.589)	-62.38 (± 31.104)	-64.07 (± 16.853)	-52.47 (± 31.788)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-75.08 (± 21.563)	-63.79 (± 31.710)	-64.24 (± 20.730)	-53.95 (± 35.053)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-74.34 (± 22.474)	-61.12 (± 34.217)	-70.27 (± 20.037)	-54.56 (± 34.785)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-73.34 (± 22.409)	-57.94 (± 33.953)	-58.19 (± 33.365)	-52.89 (± 34.032)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-74.37 (± 23.066)	-54.55 (± 34.719)	-67.92 (± 35.766)	-54.29 (± 35.851)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-69.62 (± 29.104)	-52.47 (± 35.396)	-65.97 (± 34.709)	-56.19 (± 34.460)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 31, 5, 33, 16)	-60.13 (\pm 33.848)			
Week 28 (N= 13, 34, 12, 28, 12, 31, 7, 34, 13)	-62.81 (\pm 36.300)			
Week 32 (N= 13, 34, 11, 28, 12, 32, 7, 32, 15)	-56.11 (\pm 38.003)			
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-58.72 (\pm 36.827)			
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-54.24 (\pm 36.614)			
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-55.26 (\pm 39.204)			
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-56.30 (\pm 39.696)			
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-58.86 (\pm 40.701)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Affected Body Surface Area (BSA) From Baseline (Part 1)

End point title	Absolute Change in Affected Body Surface Area (BSA) From Baseline (Part 1)
End point description:	The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.
End point type	Secondary
End point timeframe:	Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of body surface				
arithmetic mean (standard deviation)				
Week 2 (N= 32, 36, 36, 39, 38)	-4.50 (\pm 10.610)	-5.61 (\pm 10.165)	-9.08 (\pm 15.999)	-7.41 (\pm 12.588)
Week 4 (N= 76, 74, 76, 77, 75)	-12.83 (\pm 15.922)	-10.16 (\pm 12.917)	-13.34 (\pm 17.347)	-12.51 (\pm 16.318)

Week 8 (N= 70, 70, 75, 76, 72)	-19.37 (± 18.857)	-15.77 (± 17.004)	-17.55 (± 21.064)	-19.11 (± 18.253)
Week 12 (N= 70, 70, 72, 77, 70)	-24.13 (± 18.097)	-19.54 (± 19.578)	-21.94 (± 22.715)	-24.14 (± 19.903)
Week 16 (N= 70, 69, 73, 76, 68)	-26.91 (± 20.286)	-22.71 (± 21.966)	-21.74 (± 24.799)	-26.04 (± 20.403)
Week 20 (N= 67, 69, 72, 72, 67)	-30.25 (± 21.850)	-23.33 (± 22.600)	-24.35 (± 26.238)	-24.63 (± 21.263)
Week 24 (N= 71, 68, 70, 70, 67)	-31.35 (± 22.434)	-21.82 (± 21.882)	-22.66 (± 27.317)	-25.77 (± 22.085)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of body surface				
arithmetic mean (standard deviation)				
Week 2 (N= 32, 36, 36, 39, 38)	-4.84 (± 9.113)			
Week 4 (N= 76, 74, 76, 77, 75)	-9.67 (± 16.941)			
Week 8 (N= 70, 70, 75, 76, 72)	-10.00 (± 17.375)			
Week 12 (N= 70, 70, 72, 77, 70)	-11.46 (± 17.035)			
Week 16 (N= 70, 69, 73, 76, 68)	-8.87 (± 16.956)			
Week 20 (N= 67, 69, 72, 72, 67)	-11.04 (± 19.653)			
Week 24 (N= 71, 68, 70, 70, 67)	-10.45 (± 20.837)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Affected Body Surface Area (BSA) From Baseline (Part 2)

End point title	Absolute Change in Affected Body Surface Area (BSA) From Baseline (Part 2)
End point description: The Full Analysis Set (FAS2) for Part 2 included all re-randomized at Week 24. Only those participants with data available at specified timepoints were reported.	
End point type	Secondary
End point timeframe: Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52	

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: percentage of body surface				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28 12, 31, 5, 33, 16)	-46.92 (± 22.009)	-37.94 (± 18.723)	-37.17 (± 17.994)	-28.14 (± 21.790)
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 13)	-48.69 (± 23.329)	-38.68 (± 20.582)	-35.92 (± 20.804)	-25.54 (± 22.718)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-47.15 (± 25.271)	-36.62 (± 23.049)	-29.64 (± 25.590)	-23.21 (± 23.710)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-46.00 (± 26.242)	-33.61 (± 24.187)	-28.30 (± 26.437)	-22.21 (± 23.857)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-46.62 (± 26.314)	-32.94 (± 24.589)	-29.18 (± 24.774)	-22.57 (± 23.841)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-47.23 (± 26.540)	-33.22 (± 24.143)	-29.73 (± 25.503)	-22.21 (± 23.706)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-35.69 (± 26.183)	-32.72 (± 25.358)	-28.30 (± 26.378)	-22.50 (± 24.053)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-35.54 (± 26.384)	-29.48 (± 22.232)	-29.55 (± 25.359)	-22.46 (± 23.562)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: percentage of body surface				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28 12, 31, 5, 33, 16)	-41.17 (± 22.982)	-33.81 (± 26.454)	-40.60 (± 26.006)	-34.30 (± 19.787)
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 13)	-40.00 (± 23.394)	-35.61 (± 25.720)	-37.14 (± 23.801)	-33.62 (± 19.692)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-42.08 (± 22.685)	-35.94 (± 26.193)	-38.00 (± 23.847)	-32.13 (± 21.515)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-41.67 (± 23.051)	-35.75 (± 25.664)	-37.86 (± 24.674)	-30.91 (± 24.288)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-41.45 (± 23.729)	-33.41 (± 22.649)	-39.57 (± 24.758)	-32.00 (± 23.697)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-42.17 (± 25.283)	-31.91 (± 22.069)	-34.43 (± 25.172)	-32.23 (± 23.250)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-42.92 (± 25.336)	-30.53 (± 23.544)	-36.43 (± 21.141)	-31.13 (± 26.208)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-45.09 (± 25.770)	-29.66 (± 23.818)	-34.71 (± 18.688)	-33.33 (± 22.702)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percentage of body surface				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28 12, 31, 5, 33, 16)	-32.06 (\pm 22.831)			
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 13)	-36.00 (\pm 24.553)			
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-30.07 (\pm 22.861)			
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-31.27 (\pm 24.391)			
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-31.27 (\pm 24.566)			
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-27.43 (\pm 20.478)			
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-26.93 (\pm 20.775)			
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-27.21 (\pm 20.955)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Affected Body Surface Area (BSA) From Baseline (Part 1)

End point title	Percentage Change in Affected Body Surface Area (BSA) From Baseline (Part 1)
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End point description:

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 2, 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 2 (N= 32, 36, 36, 39, 38)	-10.11 (\pm 24.013)	-12.23 (\pm 26.053)	-19.43 (\pm 30.139)	-15.06 (\pm 37.312)
Week 4 (N= 76, 74, 76, 77, 75)	-26.45 (\pm 28.733)	-23.44 (\pm 28.941)	-29.46 (\pm 32.934)	-28.84 (\pm 38.412)

Week 8 (N= 70, 70, 75, 76, 72)	-39.12 (± 31.915)	-36.01 (± 35.268)	-37.60 (± 36.988)	-42.84 (± 33.931)
Week 12 (N= 70, 70, 72, 77, 70)	-49.88 (± 29.737)	-43.68 (± 38.140)	-47.04 (± 40.519)	-52.16 (± 35.736)
Week 16 (N= 70, 69, 73, 76, 68)	-54.58 (± 32.206)	-49.44 (± 40.861)	-46.35 (± 43.511)	-56.36 (± 35.593)
Week 20 (N= 67, 69, 72, 72, 67)	-59.75 (± 33.804)	-51.07 (± 42.023)	-50.36 (± 45.871)	-53.55 (± 42.762)
Week 24 (N= 71, 68, 70, 70, 67)	-63.02 (± 36.184)	-49.42 (± 43.012)	-48.11 (± 48.748)	-52.94 (± 44.872)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 2 (N= 32, 36, 36, 39, 38)	-11.45 (± 22.767)			
Week 4 (N= 76, 74, 76, 77, 75)	-20.92 (± 38.260)			
Week 8 (N= 70, 70, 75, 76, 72)	-21.24 (± 40.914)			
Week 12 (N= 70, 70, 72, 77, 70)	-26.56 (± 36.705)			
Week 16 (N= 70, 69, 73, 76, 68)	-22.37 (± 40.483)			
Week 20 (N= 67, 69, 72, 72, 67)	-25.46 (± 42.034)			
Week 24 (N= 71, 68, 70, 70, 67)	-23.76 (± 44.394)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Affected Body Surface Area (BSA) From Baseline (Part 2)

End point title	Percentage Change in Affected Body Surface Area (BSA) From Baseline (Part 2)
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End point description:

The Full Analysis Set (FAS2) for Part 2 included all re-randomized participants at Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28 12, 31, 5, 33, 16)	-88.09 (± 12.983)	-78.75 (± 27.966)	-80.67 (± 27.843)	-67.85 (± 39.902)
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 13)	-90.51 (± 10.816)	-79.51 (± 29.501)	-76.55 (± 35.680)	-62.09 (± 42.748)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-83.58 (± 23.940)	-75.09 (± 36.907)	-65.07 (± 49.743)	-55.89 (± 45.768)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-81.56 (± 27.924)	-68.81 (± 40.261)	-61.93 (± 51.222)	-53.48 (± 45.933)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-82.62 (± 28.019)	-66.33 (± 41.876)	-64.54 (± 49.422)	-54.92 (± 47.035)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-83.52 (± 28.118)	-66.91 (± 41.122)	-65.54 (± 49.945)	-53.82 (± 46.414)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-69.37 (± 40.195)	-64.74 (± 42.092)	-62.01 (± 51.359)	-52.52 (± 47.479)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-68.90 (± 40.301)	-61.59 (± 42.339)	-64.90 (± 49.605)	-52.82 (± 47.733)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28 12, 31, 5, 33, 16)	-85.29 (± 19.008)	-71.05 (± 39.900)	-80.52 (± 14.717)	-74.02 (± 31.419)
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 13)	-81.75 (± 24.996)	-73.28 (± 40.454)	-88.57 (± 5.800)	-72.98 (± 30.947)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-86.34 (± 18.724)	-74.61 (± 40.429)	-90.31 (± 10.263)	-66.90 (± 35.357)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-85.33 (± 18.348)	-74.73 (± 40.570)	-89.70 (± 10.552)	-63.85 (± 46.152)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-86.81 (± 17.237)	-72.10 (± 41.016)	-94.09 (± 5.083)	-66.00 (± 43.207)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-84.47 (± 24.104)	-69.38 (± 41.133)	-81.11 (± 19.107)	-66.54 (± 41.241)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-85.70 (± 19.040)	-64.73 (± 42.700)	-87.79 (± 16.209)	-62.58 (± 48.827)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-89.06 (± 14.176)	-62.25 (± 42.451)	-85.46 (± 16.921)	-68.75 (± 39.935)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28 12, 31, 5, 33, 16)	-72.91 (± 34.317)			
Week 28 (N= 13, 34, 12, 28 12, 31, 7, 34, 13)	-75.14 (± 37.955)			
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-69.74 (± 38.644)			
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-72.34 (± 39.621)			
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-72.08 (± 39.691)			
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-70.30 (± 40.560)			
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-68.01 (± 40.428)			
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 30, 14)	-68.78 (± 41.236)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Patient Oriented Eczema Measure (POEM) From Baseline (Part 1)

End point title	Absolute Change in Patient Oriented Eczema Measure (POEM) From Baseline (Part 1)
End point description:	
POEM is a 7-item (dryness, itching, flaking, cracking, sleep loss, bleeding, and weeping) questionnaire to assess frequency of disease symptoms with a scoring system of 0 to 28. The higher score indicating higher severity.	
The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.	
End point type	Secondary
End point timeframe:	
Baseline to Weeks 4, 8, 12, 16, 20 and 24	

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N= 75, 74, 76, 77, 75)	-4.40 (± 6.403)	-4.01 (± 6.287)	-5.42 (± 6.498)	-4.08 (± 5.448)

Week 8 (N= 70, 70, 74, 76, 72)	-7.03 (± 6.869)	-5.13 (± 7.093)	-5.70 (± 6.943)	-6.75 (± 6.646)
Week 12 (N= 69, 70, 72, 77, 70)	-7.87 (± 7.286)	-6.50 (± 7.229)	-7.29 (± 7.216)	-7.36 (± 7.460)
Week 16 (N= 69, 69, 73, 76, 68)	-8.28 (± 7.286)	-7.23 (± 7.744)	-7.19 (± 7.720)	-7.32 (± 7.017)
Week 20 (N= 66, 69, 72, 72, 67)	-9.39 (± 7.577)	-7.13 (± 8.662)	-8.10 (± 8.150)	-7.39 (± 7.721)
Week 24 (N= 70, 68, 70, 70, 67)	-9.96 (± 7.888)	-7.21 (± 8.213)	-7.86 (± 8.572)	-7.64 (± 7.011)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (N= 75, 74, 76, 77, 75)	-2.32 (± 5.910)			
Week 8 (N= 70, 70, 74, 76, 72)	-2.13 (± 6.400)			
Week 12 (N= 69, 70, 72, 77, 70)	-2.26 (± 6.088)			
Week 16 (N= 69, 69, 73, 76, 68)	-2.37 (± 6.867)			
Week 20 (N= 66, 69, 72, 72, 67)	-2.33 (± 6.821)			
Week 24 (N= 70, 68, 70, 70, 67)	-2.19 (± 7.310)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Patient Oriented Eczema Measure (POEM) From Baseline (Part 2)

End point title	Absolute Change in Patient Oriented Eczema Measure (POEM) From Baseline (Part 2)
End point description:	
POEM is a 7-item (dryness, itching, flaking, cracking, sleep loss, bleeding, and weeping) questionnaire to assess frequency of disease symptoms with a scoring system of 0 to 28. The higher score indicating higher severity.	
The Full Analysis Set (FAS2) for Part 2 included all re-randomized participants at Week 24. Only those participants with data available at specified timepoints were reported.	
End point type	Secondary
End point timeframe:	
Baseline to Weeks 24, 32, 36, 40, 44, 48 and 52	

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-15.31 (± 6.061)	-11.97 (± 6.410)	-11.58 (± 8.586)	-9.25 (± 8.347)
Week 32 (N= 13, 30, 11, 28, 12, 31, 7, 31, 13)	-14.69 (± 8.499)	-10.23 (± 8.320)	-11.91 (± 8.240)	-6.79 (± 8.875)
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-13.23 (± 8.738)	-9.91 (± 8.129)	-11.90 (± 7.264)	-7.00 (± 8.932)
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-13.92 (± 8.411)	-9.10 (± 8.715)	-11.00 (± 6.633)	-7.82 (± 9.302)
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-13.31 (± 8.460)	-9.81 (± 8.920)	-10.45 (± 6.699)	-6.50 (± 8.804)
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-11.69 (± 9.861)	-10.39 (± 8.519)	-11.50 (± 6.916)	-7.50 (± 9.836)
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-11.85 (± 10.148)	-9.13 (± 8.320)	-11.36 (± 6.889)	-6.82 (± 9.318)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-11.75 (± 7.086)	-10.42 (± 7.580)	-14.00 (± 6.205)	-9.45 (± 7.155)
Week 32 (N= 13, 30, 11, 28, 12, 31, 7, 31, 13)	-12.83 (± 7.082)	-11.32 (± 8.113)	-11.29 (± 10.323)	-9.42 (± 7.784)
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-13.00 (± 7.019)	-11.75 (± 8.370)	-12.57 (± 9.502)	-8.66 (± 7.790)
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-11.73 (± 8.162)	-11.88 (± 8.698)	-11.29 (± 8.995)	-8.81 (± 8.300)
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-11.92 (± 8.262)	-10.19 (± 8.31)	-7.86 (± 7.515)	-8.71 (± 8.158)
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-11.75 (± 9.836)	-10.33 (± 8.125)	-9.57 (± 9.126)	-9.90 (± 8.660)
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-10.64 (± 10.053)	-8.55 (± 8.240)	-10.00 (± 9.452)	-8.58 (± 9.164)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
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Subject group type	Reporting group			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-8.75 (± 7.197)			
Week 32 (N= 13, 30, 11, 28, 12, 31, 7, 31, 13)	-7.62 (± 8.856)			
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-7.93 (± 7.966)			
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-7.50 (± 7.714)			
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-7.93 (± 7.908)			
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-7.50 (± 8.438)			
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-8.50 (± 9.146)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Patient Oriented Eczema Measure (POEM) From Baseline (Part 1)

End point title	Percentage Change in Patient Oriented Eczema Measure (POEM) From Baseline (Part 1)
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End point description:

POEM is a 7-item (dryness, itching, flaking, cracking, sleep loss, bleeding, and weeping) questionnaire to assess frequency of disease symptoms with a scoring system of 0 to 28. The higher score indicating higher severity.

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 4, 8, 12, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 4 (N= 75, 73, 76, 77, 75)	-20.81 (± 34.179)	-21.02 (± 31.360)	-22.77 (± 30.783)	-17.94 (± 30.152)
Week 8 (N= 70, 69, 74, 76, 72)	-33.06 (± 41.272)	-26.52 (± 33.397)	-26.62 (± 34.946)	-34.60 (± 31.584)
Week 12 (N= 69, 69, 72, 77, 70)	-36.22 (± 43.169)	-32.42 (± 32.145)	-33.33 (± 33.732)	-34.61 (± 34.275)

Week 16 (N= 69, 68, 73, 76, 68)	-37.08 (± 52.391)	-34.71 (± 34.574)	-32.78 (± 36.449)	-35.49 (± 32.862)
Week 20 (N= 66, 68, 72, 72, 67)	-44.03 (± 38.850)	-34.23 (± 38.938)	-37.38 (± 38.448)	-35.37 (± 36.589)
Week 24 (N= 70, 67, 70, 70, 67)	-44.69 (± 61.808)	-33.91 (± 48.273)	-36.65 (± 40.947)	-36.81 (± 34.444)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 4 (N= 75, 73, 76, 77, 75)	-8.99 (± 39.554)			
Week 8 (N= 70, 69, 74, 76, 72)	-6.28 (± 42.851)			
Week 12 (N= 69, 69, 72, 77, 70)	-8.04 (± 41.445)			
Week 16 (N= 69, 68, 73, 76, 68)	-8.12 (± 45.515)			
Week 20 (N= 66, 68, 72, 72, 67)	-8.32 (± 44.942)			
Week 24 (N= 70, 67, 70, 70, 67)	-6.98 (± 49.837)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Patient Oriented Eczema Measure (POEM) From Baseline (Part 2)

End point title	Percentage Change in Patient Oriented Eczema Measure (POEM) From Baseline (Part 2)
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End point description:

POEM is a 7-item (dryness, itching, flaking, cracking, sleep loss, bleeding, and weeping) questionnaire to assess frequency of disease symptoms with a scoring system of 0 to 28. The higher score indicating higher severity.

The Full Analysis Set (FAS2) for Part 2 included all re-randomized participants at Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 32, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-72.61 (± 19.898)	-61.00 (± 30.657)	-54.05 (± 38.147)	-46.08 (± 37.356)
Week 32 (N= 13, 30, 11, 28, 12, 31, 7, 31, 13)	-64.90 (± 38.029)	-50.03 (± 44.543)	-56.00 (± 35.875)	-30.61 (± 39.689)
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-60.09 (± 40.508)	-48.61 (± 43.883)	-57.09 (± 34.068)	-33.73 (± 38.724)
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-62.85 (± 38.659)	-44.35 (± 45.524)	-54.47 (± 35.815)	-37.89 (± 40.032)
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-60.83 (± 40.648)	-48.48 (± 47.524)	-52.24 (± 36.218)	-30.25 (± 43.110)
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-54.56 (± 46.380)	-51.53 (± 44.857)	-55.93 (± 35.043)	-35.37 (± 42.309)
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-54.68 (± 45.987)	-44.51 (± 43.725)	-54.47 (± 34.319)	-29.38 (± 46.373)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-60.03 (± 30.545)	-51.61 (± 35.438)	-64.00 (± 20.049)	-45.63 (± 34.579)
Week 32 (N= 13, 30, 11, 28, 12, 31, 7, 31, 13)	-64.21 (± 28.981)	-55.82 (± 36.229)	-47.30 (± 57.463)	-46.42 (± 38.011)
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-66.78 (± 27.084)	-57.38 (± 37.436)	-57.54 (± 59.987)	-43.35 (± 40.000)
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-58.98 (± 33.289)	-58.12 (± 38.754)	-49.79 (± 55.862)	-43.75 (± 40.933)
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-59.17 (± 35.572)	-50.10 (± 37.814)	-36.09 (± 53.637)	-43.16 (± 39.688)
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-58.18 (± 46.077)	-51.56 (± 39.299)	-44.04 (± 58.904)	-50.45 (± 41.809)
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-52.64 (± 47.556)	-43.45 (± 42.459)	-48.82 (± 63.478)	-43.01 (± 45.577)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
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Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-47.92 (± 40.572)			
Week 32 (N= 13, 30, 11, 28, 12, 31, 7, 31, 13)	-43.95 (± 50.962)			
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-44.58 (± 45.387)			
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-42.88 (± 45.567)			
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-46.19 (± 46.429)			
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-43.48 (± 48.292)			
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-47.62 (± 50.785)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Dermatology Life Quality Index (DLQI) From Baseline (Part 1)

End point title	Absolute Change in Dermatology Life Quality Index (DLQI) From Baseline (Part 1)
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End point description:

DLQI is a questionnaire with a score system of 0 to 30 the high score is indicative of poor QoL. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline at Weeks 2, 8, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: score on the scale				
arithmetic mean (standard deviation)				
Week 2 (N= 71, 77, 75, 75, 78)	-3.63 (± 4.992)	-2.82 (± 4.850)	-3.32 (± 5.745)	-3.40 (± 5.131)
Week 8 (N= 70, 69, 74, 76, 72)	-6.13 (± 6.164)	-5.59 (± 5.553)	-5.08 (± 7.252)	-7.13 (± 5.954)
Week 16 (N= 67, 67, 73, 76, 68)	-7.79 (± 6.832)	-6.25 (± 6.246)	-6.47 (± 7.835)	-7.76 (± 6.265)
Week 20 (N= 66, 69, 72, 72, 67)	-7.89 (± 6.848)	-6.42 (± 6.833)	-6.97 (± 8.512)	-7.31 (± 7.132)

Week 24 (N= 70, 68, 70, 70, 67)	-8.33 (± 7.036)	-6.54 (± 6.384)	-6.74 (± 8.681)	-7.69 (± 7.230)
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End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: score on the scale				
arithmetic mean (standard deviation)				
Week 2 (N= 71, 77, 75, 75, 78)	-2.09 (± 4.710)			
Week 8 (N= 70, 69, 74, 76, 72)	-2.43 (± 5.466)			
Week 16 (N= 67, 67, 73, 76, 68)	-2.35 (± 6.069)			
Week 20 (N= 66, 69, 72, 72, 67)	-2.39 (± 6.391)			
Week 24 (N= 70, 68, 70, 70, 67)	-2.30 (± 6.406)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Dermatology Life Quality Index (DLQI) From Baseline (Part 2)

End point title	Absolute Change in Dermatology Life Quality Index (DLQI) From Baseline (Part 2)
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End point description:

DLQI is a questionnaire with a score system of 0 to 30 the high score is indicative of poor QoL. The Full Analysis Set (FAS2) for Part 2 included all re-randomized at Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: score on scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-12.54 (± 6.703)	-9.00 (± 6.290)	-9.08 (± 6.487)	-7.57 (± 7.295)

Week 28 (N= 13, 33, 12, 28, 12, 31, 7, 34, 13)	-12.62 (± 8.191)	-9.52 (± 6.929)	-9.83 (± 6.658)	-7.21 (± 6.488)
Week 32 (N= 13, 33, 11, 28, 12, 32, 7, 32, 15)	-12.38 (± 8.272)	-8.00 (± 7.612)	-8.55 (± 8.238)	-5.75 (± 7.183)
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-11.85 (± 8.122)	-7.72 (± 7.985)	-7.90 (± 6.903)	-6.18 (± 7.222)
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-12.23 (± 7.715)	-7.07 (± 8.073)	-7.18 (± 5.456)	-6.21 (± 7.279)
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-11.38 (± 8.109)	-7.19 (± 7.943)	-8.18 (± 6.258)	-5.68 (± 7.029)
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-9.92 (± 6.800)	-7.29 (± 8.022)	-8.40 (± 7.516)	-6.21 (± 7.218)
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-9.08 (± 6.652)	-6.83 (± 7.852)	-8.09 (± 7.077)	-5.93 (± 7.383)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: score on scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-11.42 (± 7.115)	-8.26 (± 9.338)	-15.40 (± 8.562)	-9.67 (± 7.712)
Week 28 (N= 13, 33, 12, 28, 12, 31, 7, 34, 13)	-11.33 (± 7.832)	-8.45 (± 9.705)	-12.29 (± 9.232)	-9.68 (± 8.029)
Week 32 (N= 13, 33, 11, 28, 12, 32, 7, 32, 15)	-12.25 (± 7.700)	-8.50 (± 9.629)	-13.14 (± 8.050)	-9.13 (± 7.906)
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-12.58 (± 7.716)	-8.84 (± 9.893)	-14.00 (± 8.446)	-8.53 (± 7.927)
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-11.27 (± 7.976)	-8.06 (± 9.844)	-14.57 (± 7.569)	-8.23 (± 8.281)
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-12.08 (± 8.426)	-6.88 (± 9.587)	-10.29 (± 7.889)	-8.26 (± 8.058)
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-11.92 (± 8.229)	-6.83 (± 9.322)	-11.29 (± 6.237)	-7.93 (± 7.891)
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-12.55 (± 9.136)	-6.41 (± 9.428)	-11.57 (± 6.705)	-8.10 (± 7.752)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: score on scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-6.44 (± 7.420)			
Week 28 (N= 13, 33, 12, 28, 12, 31, 7, 34, 13)	-5.77 (± 8.633)			

Week 32 (N= 13, 33, 11, 28, 12, 32, 7, 32, 15)	-5.47 (± 7.963)			
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-5.93 (± 7.839)			
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-5.36 (± 8.308)			
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-5.93 (± 6.889)			
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-6.79 (± 7.040)			
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-6.64 (± 6.902)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Dermatology Life Quality Index (DLQI) From Baseline (Part 1)

End point title	Percentage Change in Dermatology Life Quality Index (DLQI) From Baseline (Part 1)
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End point description:

DLQI is a questionnaire with a score system of 0 to 30 the high score is indicative of poor QoL. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 2, 8, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 2 (N= 71, 77, 75, 74, 78)	-22.68 (± 31.305)	-11.95 (± 47.921)	-16.80 (± 41.680)	-22.73 (± 32.711)
Week 8 (N= 70, 69, 74, 75, 72)	-36.87 (± 36.954)	-36.14 (± 41.176)	-27.54 (± 59.199)	-45.85 (± 32.198)
Week 16 (N= 67, 67, 73, 75, 68)	-46.69 (± 40.563)	-41.27 (± 43.616)	-34.02 (± 62.565)	-48.96 (± 29.801)
Week 20 (N= 66, 69, 72, 72, 67)	-47.48 (± 40.616)	-42.90 (± 46.336)	-35.79 (± 67.398)	-44.33 (± 36.816)
Week 24 (N= 70, 68, 70, 70, 67)	-51.84 (± 41.442)	-42.36 (± 45.550)	-33.28 (± 72.816)	-45.63 (± 33.860)

End point values	Placebo (Part 1)			
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Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 2 (N= 71, 77, 75, 74, 78)	-10.30 (± 37.999)			
Week 8 (N= 70, 69, 74, 75, 72)	-13.12 (± 42.775)			
Week 16 (N= 67, 67, 73, 75, 68)	-11.35 (± 51.739)			
Week 20 (N= 66, 69, 72, 72, 67)	-12.08 (± 49.973)			
Week 24 (N= 70, 68, 70, 70, 67)	-11.91 (± 55.694)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Dermatology Life Quality Index (DLQI) From Baseline (Part 2)

End point title	Percentage Change in Dermatology Life Quality Index (DLQI) From Baseline (Part 2)
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End point description:

DLQI is a questionnaire with a score system of 0 to 30 the high score is indicative of poor QoL. The Full Analysis Set (FAS2) for Part 2 included all re-randomized Participants at week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-75.53 (± 26.705)	-61.64 (± 35.809)	-64.74 (± 31.091)	-44.26 (± 57.217)
Week 28 (N= 13, 33, 12, 28, 12, 31, 7, 34, 13)	-72.50 (± 37.184)	-62.65 (± 43.216)	-71.77 (± 29.970)	-44.81 (± 56.575)
Week 32 (N= 13, 33, 11, 28, 12, 32, 7, 32, 15)	-68.19 (± 38.039)	-48.69 (± 56.833)	-61.68 (± 42.315)	-31.65 (± 55.087)
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-65.76 (± 35.792)	-48.12 (± 56.610)	-60.50 (± 41.018)	-35.86 (± 58.071)
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-69.26 (± 34.172)	-44.78 (± 59.798)	-58.29 (± 42.112)	-36.52 (± 58.909)

Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-63.03 (± 41.237)	-45.33 (± 60.470)	-63.04 (± 42.005)	-33.25 (± 58.480)
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-59.02 (± 36.676)	-45.68 (± 59.933)	-63.97 (± 43.622)	-35.98 (± 57.915)
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-53.62 (± 36.496)	-43.64 (± 56.804)	-61.04 (± 42.716)	-33.21 (± 59.514)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-72.47 (± 27.818)	-47.08 (± 82.439)	-70.77 (± 27.653)	-55.36 (± 33.443)
Week 28 (N= 13, 33, 12, 28, 12, 31, 7, 34, 13)	-70.02 (± 28.760)	-48.86 (± 83.936)	-65.28 (± 26.807)	-55.62 (± 34.382)
Week 32 (N= 13, 33, 11, 28, 12, 32, 7, 32, 15)	-77.14 (± 26.277)	-50.15 (± 83.141)	-72.98 (± 17.074)	-52.99 (± 36.735)
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-79.13 (± 24.980)	-52.16 (± 84.141)	-78.26 (± 23.932)	-49.48 (± 43.137)
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-72.31 (± 27.268)	-46.41 (± 84.277)	-83.18 (± 16.284)	-49.75 (± 42.024)
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-76.32 (± 31.166)	-39.27 (± 83.804)	-60.44 (± 28.925)	-49.15 (± 43.228)
Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-73.10 (± 28.704)	-40.20 (± 84.240)	-70.04 (± 26.437)	-50.82 (± 41.018)
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-72.35 (± 33.768)	-35.27 (± 85.953)	-71.56 (± 28.287)	-49.24 (± 43.003)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 28, 12, 31, 5, 33, 16)	-48.30 (± 57.726)			
Week 28 (N= 13, 33, 12, 28, 12, 31, 7, 34, 13)	-41.13 (± 80.192)			
Week 32 (N= 13, 33, 11, 28, 12, 32, 7, 32, 15)	-41.18 (± 68.097)			
Week 36 (N= 13, 32, 10, 28, 12, 32, 7, 32, 14)	-45.04 (± 65.630)			
Week 40 (N= 13, 30, 11, 28, 11, 32, 7, 31, 14)	-38.69 (± 80.196)			
Week 44 (N= 13, 31, 11, 28, 12, 32, 7, 31, 14)	-48.21 (± 48.871)			

Week 48 (N= 13, 31, 10, 28, 12, 30, 7, 30, 14)	-57.92 (\pm 45.339)			
Week 52 (N= 13, 30, 11, 28, 11, 29, 7, 31, 14)	-57.12 (\pm 44.899)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Atopic Dermatitis Control Tool (ADCT) From Baseline (Part 1)

End point title	Absolute Change in Atopic Dermatitis Control Tool (ADCT) From Baseline (Part 1)
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End point description:

ADCT is a questionnaire to assess patient-self-perceived control of their eczema with a total score from 0 to 24; higher scores indicate lower AD control.

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 16 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: score on scale				
arithmetic mean (standard deviation)				
Week 16 (N= 67, 66, 73, 76, 68)	-6.70 (\pm 5.813)	-5.41 (\pm 6.054)	-6.22 (\pm 6.272)	-6.61 (\pm 5.804)
Week 24 (N= 65, 66, 70, 68, 67)	-7.35 (\pm 6.695)	-5.80 (\pm 6.187)	-6.70 (\pm 6.566)	-6.66 (\pm 5.868)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: score on scale				
arithmetic mean (standard deviation)				
Week 16 (N= 67, 66, 73, 76, 68)	-2.50 (\pm 4.589)			
Week 24 (N= 65, 66, 70, 68, 67)	-1.90 (\pm 5.046)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Atopic Dermatitis Control Tool (ADCT) From Baseline (Part 2)

End point title	Absolute Change in Atopic Dermatitis Control Tool (ADCT) From Baseline (Part 2)
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End point description:

ADCT is a questionnaire to assess patient-self-perceived control of their eczema with a total score from 0 to 24; higher scores indicate lower AD control.

The Full Analysis Set (FAS2) for Part 2 included all re-randomized at week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to weeks 24, 36 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 28, 12, 27, 12, 31, 5, 31, 16)	-11.23 (± 6.071)	-8.64 (± 5.927)	-9.83 (± 6.506)	-7.44 (± 5.673)
Week 36 (N= 13, 30, 10, 27, 12, 31, 7, 31, 12)	-11.46 (± 5.681)	-8.13 (± 6.463)	-8.20 (± 6.143)	-7.78 (± 6.123)
Week 52 (N= 13, 30, 11, 27, 11, 29, 7, 29, 14)	-11.31 (± 4.768)	-8.30 (± 5.706)	-8.82 (± 6.809)	-7.44 (± 6.594)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 28, 12, 27, 12, 31, 5, 31, 16)	-9.83 (± 5.132)	-8.42 (± 6.386)	-12.60 (± 6.986)	-8.29 (± 5.996)
Week 36 (N= 13, 30, 10, 27, 12, 31, 7, 31, 12)	-10.33 (± 5.483)	-9.26 (± 6.875)	-10.71 (± 6.550)	-8.03 (± 6.385)
Week 52 (N= 13, 30, 11, 27, 11, 29, 7, 29, 14)	-10.45 (± 5.989)	-6.48 (± 6.539)	-9.71 (± 4.751)	-8.34 (± 6.893)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 28, 12, 27, 12, 31, 5, 31, 16)	-6.25 (± 6.083)			
Week 36 (N= 13, 30, 10, 27, 12, 31, 7, 31, 12)	-6.38 (± 6.063)			
Week 52 (N= 13, 30, 11, 27, 11, 29, 7, 29, 14)	-7.14 (± 6.125)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Atopic Dermatitis Control Tool (ADCT) From Baseline (Part 1)

End point title	Percentage Change in Atopic Dermatitis Control Tool (ADCT) From Baseline (Part 1)
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End point description:

ADCT is a questionnaire to assess patient-self-perceived control of their eczema with a total score from 0 to 24; higher scores indicate lower AD control.

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints are reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 16 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 16 (N= 67, 66, 73, 76, 68)	-40.56 (± 37.340)	-33.42 (± 34.745)	-36.42 (± 37.103)	-38.72 (± 30.762)
Week 24 (N= 65, 66, 70, 68, 67)	-45.18 (± 42.438)	-36.20 (± 41.363)	-40.45 (± 40.708)	-39.35 (± 31.799)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 16 (N= 67, 66, 73, 76, 68)	-17.04 (± 32.553)			
Week 24 (N= 65, 66, 70, 68, 67)	-12.31 (± 37.504)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Atopic Dermatitis Control Tool (ADCT) From Baseline (Part 2)

End point title	Percentage Change in Atopic Dermatitis Control Tool (ADCT) From Baseline (Part 2)
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End point description:

ADCT is a questionnaire to assess patient-self-perceived control of their eczema with a total score from 0 to 24; higher scores indicate lower AD control.

The Full Analysis Set (FAS2) for Part 2 included all re-randomized at Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 36 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 28, 12, 27, 12, 31, 5, 31, 16)	-66.75 (± 32.632)	-57.08 (± 37.656)	-56.01 (± 36.112)	-49.97 (± 34.078)
Week 36 (N= 13, 30, 10, 27, 12, 31, 7, 31, 13)	-69.01 (± 29.493)	-50.38 (± 42.649)	-50.01 (± 37.199)	-50.87 (± 33.197)
Week 52 (N= 13, 30, 11, 27, 11, 29, 7, 29, 14)	-69.93 (± 26.250)	-54.77 (± 34.128)	-52.75 (± 41.167)	-47.15 (± 39.681)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-Randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-Randomized From the 62.5 mg Arm (Part 2)
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	2)			
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 28, 12, 27, 12, 31, 5, 31, 16)	-65.46 (± 26.823)	-53.10 (± 40.207)	-63.92 (± 29.784)	-50.66 (± 33.458)
Week 36 (N= 13, 30, 10, 27, 12, 31, 7, 31, 13)	-69.73 (± 28.925)	-58.44 (± 43.340)	-62.63 (± 23.130)	-48.59 (± 38.274)
Week 52 (N= 13, 30, 11, 27, 11, 29, 7, 29, 14)	-67.84 (± 32.469)	-41.39 (± 43.875)	-64.19 (± 28.274)	-50.29 (± 41.341)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 28, 12, 27, 12, 31, 5, 31, 16)	-44.95 (± 45.331)			
Week 36 (N= 13, 30, 10, 27, 12, 31, 7, 31, 13)	-49.42 (± 45.902)			
Week 52 (N= 13, 30, 11, 27, 11, 29, 7, 29, 14)	-53.35 (± 47.196)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Hospital Anxiety and Depression Scale (HADS) From Baseline (Part 1)

End point title	Absolute Change in Hospital Anxiety and Depression Scale (HADS) From Baseline (Part 1)
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End point description:

The HADS is 14-item questionnaire with two subscales: anxiety & depression. Each subscale (anxiety & depression) ranges 0-21. The total HADS score ranges 0-42 with higher score indicating a poorer state. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 8, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 8 (N= 70, 68, 74, 76, 72)	-2.20 (± 4.639)	-2.07 (± 6.194)	-2.35 (± 5.641)	-3.29 (± 5.132)
Week 16 (N= 67, 66, 73, 76, 68)	-2.67 (± 5.761)	-2.53 (± 6.510)	-3.04 (± 6.292)	-3.74 (± 6.401)
Week 20 (N= 66, 68, 72, 72, 67)	-2.52 (± 7.254)	-2.35 (± 7.326)	-3.38 (± 6.787)	-4.24 (± 5.873)
Week 24 (N= 70, 67, 70, 70, 67)	-2.96 (± 7.550)	-2.30 (± 6.880)	-2.83 (± 6.818)	-4.00 (± 6.802)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 8 (N= 70, 68, 74, 76, 72)	-0.97 (± 3.940)			
Week 16 (N= 67, 66, 73, 76, 68)	-0.57 (± 5.088)			
Week 20 (N= 66, 68, 72, 72, 67)	-0.66 (± 4.176)			
Week 24 (N= 70, 67, 70, 70, 67)	-0.97 (± 4.196)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Hospital Anxiety and Depression Scale (HADS) From Baseline (Part 2)

End point title	Absolute Change in Hospital Anxiety and Depression Scale (HADS) From Baseline (Part 2)
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End point description:

The HADS is 14-item questionnaire with two subscales: anxiety & depression. Each subscale (anxiety & depression) ranges 0-21. The total HADS score ranges 0-42 with higher score indicating a poorer state. The Full Analysis Set (FAS2) for Part 2 included all re-randomized participants at Week 24. Only those participants with data available at specified timepoints are reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 27, 12, 31, 5, 33, 16)	-4.54 (± 8.482)	-1.73 (± 7.434)	-5.58 (± 10.184)	-2.81 (± 6.822)
Week 28 (N= 13, 33, 12, 27, 12, 31, 7, 34, 13)	-3.54 (± 7.965)	-2.52 (± 6.205)	-6.50 (± 11.430)	-2.70 (± 6.916)
Week 32 (N= 13, 33, 11, 27, 12, 32, 7, 32, 15)	-3.38 (± 8.893)	-1.24 (± 6.996)	-4.09 (± 9.027)	-2.74 (± 7.593)
Week 36 (N= 13, 32, 10, 27, 12, 32, 7, 32, 14)	-1.85 (± 9.754)	-1.22 (± 8.015)	-3.80 (± 10.497)	-2.52 (± 5.833)
Week 40 (N= 13, 30, 11, 27, 11, 32, 7, 31, 14)	-2.92 (± 8.864)	-1.40 (± 6.966)	-3.09 (± 10.222)	-2.70 (± 6.151)
Week 44 (N= 13, 31, 11, 27, 12, 32, 7, 31, 14)	-2.69 (± 8.873)	-0.29 (± 6.963)	-3.45 (± 10.511)	-3.07 (± 5.313)
Week 48 (N= 13, 31, 10, 27, 12, 30, 7, 30, 14)	-3.08 (± 8.883)	-0.68 (± 7.078)	-4.40 (± 10.024)	-2.85 (± 5.559)
Week 52 (N= 13, 30, 11, 27, 11, 29, 7, 31, 14)	-2.46 (± 9.162)	-0.80 (± 7.092)	-2.55 (± 8.359)	-3.00 (± 5.877)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 27, 12, 31, 5, 33, 16)	-3.67 (± 6.998)	-4.42 (± 7.890)	-8.20 (± 6.340)	-4.03 (± 6.710)
Week 28 (N= 13, 33, 12, 27, 12, 31, 7, 34, 13)	-4.33 (± 7.679)	-4.97 (± 8.428)	-7.29 (± 5.251)	-5.26 (± 7.034)
Week 32 (N= 13, 33, 11, 27, 12, 32, 7, 32, 15)	-4.42 (± 7.242)	-5.66 (± 8.280)	-6.86 (± 5.460)	-3.97 (± 6.483)
Week 36 (N= 13, 32, 10, 27, 12, 32, 7, 32, 14)	-4.42 (± 6.999)	-5.50 (± 8.828)	-7.14 (± 4.880)	-3.75 (± 7.878)
Week 40 (N= 13, 30, 11, 27, 11, 32, 7, 31, 14)	-3.55 (± 7.594)	-5.16 (± 8.674)	-7.43 (± 5.563)	-3.29 (± 5.593)
Week 44 (N= 13, 31, 11, 27, 12, 32, 7, 31, 14)	-4.25 (± 7.225)	-4.56 (± 8.879)	-5.43 (± 5.192)	-3.71 (± 7.408)
Week 48 (N= 13, 31, 10, 27, 12, 30, 7, 30, 14)	-3.33 (± 7.797)	-5.23 (± 8.724)	-7.43 (± 5.412)	-4.17 (± 7.269)
Week 52 (N= 13, 30, 11, 27, 11, 29, 7, 31, 14)	-4.18 (± 7.167)	-4.59 (± 8.454)	-7.29 (± 5.794)	-3.13 (± 8.082)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 33, 12, 27, 12, 31, 5, 33, 16)	-0.38 (± 4.660)			
Week 28 (N= 13, 33, 12, 27, 12, 31, 7, 34, 13)	0.38 (± 4.753)			
Week 32 (N= 13, 33, 11, 27, 12, 32, 7, 32, 15)	-0.20 (± 4.491)			
Week 36 (N= 13, 32, 10, 27, 12, 32, 7, 32, 14)	0.29 (± 4.250)			
Week 40 (N= 13, 30, 11, 27, 11, 32, 7, 31, 14)	0.50 (± 5.125)			
Week 44 (N= 13, 31, 11, 27, 12, 32, 7, 31, 14)	-0.21 (± 4.318)			
Week 48 (N= 13, 31, 10, 27, 12, 30, 7, 30, 14)	-1.00 (± 4.852)			
Week 52 (N= 13, 30, 11, 27, 11, 29, 7, 31, 14)	-0.64 (± 5.719)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Hospital Anxiety and Depression Scale (HADS) From Baseline (Part 1)

End point title	Percentage Change in Hospital Anxiety and Depression Scale (HADS) From Baseline (Part 1)
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End point description:

The HADS is 14-item questionnaire with two subscales: anxiety & depression. Each subscale (anxiety & depression) ranges 0-21. The total HADS score ranges 0-42 with higher score indicating a poorer state. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 8, 16, 20 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: Percentage of change				
arithmetic mean (standard deviation)				

Week 8 (N= 69, 66, 70, 76, 69)	-18.40 (± 46.151)	-11.76 (± 48.829)	-10.22 (± 56.395)	-13.15 (± 69.427)
Week 16 (N= 66, 65, 69, 76, 65)	-18.12 (± 56.175)	-11.72 (± 54.678)	-15.84 (± 54.001)	-17.47 (± 94.346)
Week 20 (N= 65, 66, 68, 72, 64)	-20.15 (± 65.506)	-7.39 (± 62.693)	-17.62 (± 59.518)	-25.97 (± 83.249)
Week 24 (N= 69, 65, 66, 70, 64)	-13.22 (± 97.953)	-8.67 (± 60.563)	-17.75 (± 52.049)	-12.07 (± 120.061)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: Percentage of change				
arithmetic mean (standard deviation)				
Week 8 (N= 69, 66, 70, 76, 69)	-0.66 (± 77.969)			
Week 16 (N= 66, 65, 69, 76, 65)	2.82 (± 101.930)			
Week 20 (N= 65, 66, 68, 72, 64)	-5.02 (± 78.180)			
Week 24 (N= 69, 65, 66, 70, 64)	-8.17 (± 77.872)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Hospital Anxiety and Depression Scale (HADS) From Baseline (Part 2)

End point title	Percentage Change in Hospital Anxiety and Depression Scale (HADS) From Baseline (Part 2)
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End point description:

The HADS is 14-item questionnaire with two subscales: anxiety & depression. Each subscale (anxiety & depression) ranges 0-21. The total HADS score ranges 0-42 with higher score indicating a poorer state. The Full Analysis Set (FAS2) for Part 2 included all re-randomized participants at Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28

Units: Percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 32, 11, 26, 11, 29, 5, 33, 16)	-28.01 (± 54.369)	-17.89 (± 76.693)	-34.27 (± 48.841)	-13.63 (± 65.697)
Week 28 (N= 13, 32, 11, 26, 11, 29, 7, 34, 13)	-18.57 (± 53.870)	-22.56 (± 67.645)	-30.97 (± 51.945)	-17.92 (± 53.098)
Week 32 (N= 13, 32, 10, 26, 11, 30, 7, 32, 15)	-19.06 (± 60.844)	-14.02 (± 82.893)	-29.10 (± 52.035)	-20.31 (± 63.189)
Week 36 (N= 13, 31, 9, 26, 11, 30, 7, 32, 14)	11.76 (± 84.979)	-9.44 (± 81.662)	-6.28 (± 62.772)	-22.30 (± 51.020)
Week 40 (N= 13, 29, 10, 26, 10, 30, 7, 31, 14)	-13.29 (± 60.249)	-18.23 (± 79.025)	7.25 (± 82.513)	-21.32 (± 50.659)
Week 44 (N= 13, 30, 10, 26, 11, 30, 7, 31, 14)	-2.42 (± 54.527)	-5.30 (± 88.418)	-23.23 (± 56.824)	-31.88 (± 49.100)
Week 48 (N= 13, 30, 9, 26, 11, 28, 7, 30, 14)	-14.15 (± 60.660)	-4.47 (± 95.509)	-28.27 (± 51.499)	-21.89 (± 53.010)
Week 52 (N= 13, 29, 10, 26, 11, 28, 7, 31, 14)	-8.10 (± 67.182)	-7.59 (± 92.868)	-13.70 (± 44.085)	-19.98 (± 56.405)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: Percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 32, 11, 26, 11, 29, 5, 33, 16)	-20.28 (± 49.825)	-32.24 (± 65.070)	-46.94 (± 22.063)	-22.38 (± 58.898)
Week 28 (N= 13, 32, 11, 26, 11, 29, 7, 34, 13)	4.22 (± 96.782)	-30.52 (± 66.305)	-49.58 (± 31.509)	-33.17 (± 41.412)
Week 32 (N= 13, 32, 10, 26, 11, 30, 7, 32, 15)	-11.36 (± 87.084)	-43.96 (± 68.306)	-42.56 (± 27.759)	-32.62 (± 49.764)
Week 36 (N= 13, 31, 9, 26, 11, 30, 7, 32, 14)	-8.75 (± 85.214)	37.19 (± 71.372)	-51.27 (± 29.960)	-32.59 (± 49.531)
Week 40 (N= 13, 29, 10, 26, 10, 30, 7, 31, 14)	4.24 (± 91.941)	-40.11 (± 67.991)	-56.66 (± 33.879)	-35.92 (± 46.888)
Week 44 (N= 13, 30, 10, 26, 11, 30, 7, 31, 14)	-15.90 (± 85.382)	-30.93 (± 71.891)	-41.44 (± 37.143)	-32.73 (± 57.357)
Week 48 (N= 13, 30, 9, 26, 11, 28, 7, 30, 14)	4.97 (± 88.017)	-39.36 (± 69.672)	-60.77 (± 35.190)	-36.32 (± 47.746)
Week 52 (N= 13, 29, 10, 26, 11, 28, 7, 31, 14)	0.43 (± 85.522)	-14.22 (± 78.739)	-59.23 (± 37.434)	-23.84 (± 50.933)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of change				
arithmetic mean (standard deviation)				

Week 24 (N= 13, 32, 11, 26, 11, 29, 5, 33, 16)	-32.55 (± 66.184)			
Week 28 (N= 13, 32, 11, 26, 11, 29, 7, 34, 13)	-38.39 (± 77.030)			
Week 32 (N= 13, 32, 10, 26, 11, 30, 7, 32, 15)	-38.06 (± 69.176)			
Week 36 (N= 13, 31, 9, 26, 11, 30, 7, 32, 14)	-9.11 (± 110.289)			
Week 40 (N= 13, 29, 10, 26, 10, 30, 7, 31, 14)	-1.02 (± 98.096)			
Week 44 (N= 13, 30, 10, 26, 11, 30, 7, 31, 14)	-22.21 (± 80.062)			
Week 48 (N= 13, 30, 9, 26, 11, 28, 7, 30, 14)	-34.95 (± 67.833)			
Week 52 (N= 13, 29, 10, 26, 11, 28, 7, 31, 14)	-18.16 (± 69.310)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Weekly Average of Pruritus Numerical Rating Scale (NRS) From Baseline (Part 1)

End point title	Absolute Change in Weekly Average of Pruritus Numerical Rating Scale (NRS) From Baseline (Part 1)
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End point description:

The pruritus NRS is a simple assessment tool to report the intensity of their pruritus (itch) ranges from 0 to 10 with 0 being 'no itch' and 10 being the 'worst itch imaginable'.
The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 1 (N= 74, 77, 77, 77, 77)	-0.54 (± 1.096)	-0.56 (± 0.978)	-0.49 (± 0.965)	-0.45 (± 0.908)
Week 2 (N= 75, 77, 76, 76, 77)	-0.65 (± 1.316)	-0.79 (± 1.367)	-0.73 (± 1.075)	-0.81 (± 1.224)
Week 3 (N= 75, 77, 77, 77, 76)	-0.90 (± 1.619)	-0.92 (± 1.392)	-1.05 (± 1.302)	-0.88 (± 1.478)
Week 4 (N= 75, 76, 76, 77, 77)	-.096 (± 1.672)	-1.25 (± 1.657)	-1.36 (± 1.443)	-1.09 (± 1.668)
Week 5 (N= 75, 75, 75, 77, 74)	-0.99 (± 1.811)	-1.38 (± 1.653)	-1.42 (± 1.591)	-1.49 (± 1.799)

Week 6 (N= 74, 73, 75, 76, 75)	-1.09 (± 1.679)	-1.35 (± 1.818)	-1.38 (± 1.666)	-1.58 (± 2.057)
Week 7 (N= 73, 72, 74, 76, 73)	-1.25 (± 1.966)	-1.54 (± 1.850)	-1.57 (± 1.710)	-1.78 (± 2.002)
Week 8 (N= 73, 72, 73, 75, 73)	-1.42 (± 2.062)	-1.50 (± 1.786)	-1.60 (± 1.816)	-1.93 (± 2.053)
Week 9 (N= 74, 73, 74, 75, 70)	-1.44 (± 2.104)	-1.52 (± 1.805)	-1.89 (± 1.885)	-2.13 (± 2.031)
Week 10 (N= 72, 73, 72, 74, 69)	-1.62 (± 2.162)	-1.67 (± 1.852)	-1.82 (± 2.082)	-2.17 (± 2.137)
Week 11 (N= 73, 70, 73, 74, 68)	-1.68 (± 2.176)	-1.67 (± 1.936)	-2.06 (± 2.091)	-2.31 (± 2.248)
Week 12 (N= 72, 69, 71, 73, 68)	-1.70 (± 2.204)	-1.65 (± 2.074)	-1.96 (± 2.107)	-2.28 (± 2.262)
Week 13 (N= 72, 71, 71, 73, 70)	-1.83 (± 2.295)	-1.87 (± 2.247)	-2.05 (± 2.164)	-2.28 (± 2.291)
Week 14 (N= 72, 70, 70, 75, 67)	-1.82 (± 2.355)	-2.02 (± 2.468)	-2.13 (± 2.308)	-2.35 (± 2.316)
Week 15 (N= 70, 69, 71, 74, 67)	-1.87 (± 2.386)	-2.08 (± 2.511)	-2.10 (± 2.290)	-2.32 (± 2.288)
Week 16 (N= 72, 68, 71, 75, 66)	-2.06 (± 2.539)	-2.09 (± 2.497)	-2.22 (± 2.275)	-2.31 (± 2.301)
Week 17 (N= 70, 68, 71, 75, 67)	-2.13 (± 2.465)	-2.18 (± 2.457)	-2.14 (± 2.368)	-2.35 (± 2.346)
Week 18 (N= 70, 68, 68, 75, 66)	-2.18 (± 2.534)	-2.21 (± 2.543)	-2.16 (± 2.307)	-2.37 (± 2.383)
Week 19 (N= 69, 67, 70, 75, 67)	-2.19 (± 2.484)	-2.22 (± 2.563)	-2.14 (± 2.291)	-2.38 (± 2.463)
Week 20 (N= 68, 67, 69, 72, 67)	-2.28 (± 2.522)	-2.19 (± 2.530)	-2.13 (± 2.360)	-2.31 (± 2.401)
Week 21 (N= 69, 68, 70, 72, 67)	-2.28 (± 2.516)	-2.23 (± 2.576)	-2.27 (± 2.352)	-2.43 (± 2.404)
Week 22 (N= 69, 66, 69, 72, 67)	-2.38 (± 2.622)	-2.29 (± 2.699)	-2.25 (± 2.438)	-2.44 (± 2.383)
Week 23 (N= 70, 67, 70, 71, 67)	-2.56 (± 2.671)	-2.27 (± 2.538)	-2.20 (± 2.529)	-2.59 (± 2.453)
Week 24 (N= 70, 66, 70, 71, 67)	-2.58 (± 2.662)	-2.30 (± 2.672)	-2.21 (± 2.616)	-2.46 (± 2.427)

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 1 (N= 74, 77, 77, 77, 77)	-0.28 (± 1.071)			
Week 2 (N= 75, 77, 76, 76, 77)	-0.42 (± 1.046)			
Week 3 (N= 75, 77, 77, 77, 76)	-0.65 (± 1.567)			
Week 4 (N= 75, 76, 76, 77, 77)	-0.77 (± 1.744)			
Week 5 (N= 75, 75, 75, 77, 74)	-0.83 (± 2.030)			
Week 6 (N= 74, 73, 75, 76, 75)	-0.94 (± 1.899)			

Week 7 (N= 73, 72, 74, 76, 73)	-0.78 (± 1.922)			
Week 8 (N= 73, 72, 73, 75, 73)	-0.80 (± 1.979)			
Week 9 (N= 74, 73, 74, 75, 70)	-1.00 (± 2.142)			
Week 10 (N= 72, 73, 72, 74, 69)	-0.97 (± 2.244)			
Week 11 (N= 73, 70, 73, 74, 68)	-0.93 (± 2.111)			
Week 12 (N= 72, 69, 71, 73, 68)	-0.79 (± 2.162)			
Week 13 (N= 72, 71, 71, 73, 70)	-0.72 (± 2.087)			
Week 14 (N= 72, 70, 70, 75, 67)	-0.58 (± 2.055)			
Week 15 (N= 70, 69, 71, 74, 67)	-0.57 (± 2.018)			
Week 16 (N= 72, 68, 71, 75, 66)	-0.54 (± 2.077)			
Week 17 (N= 70, 68, 71, 75, 67)	-0.61 (± 2.143)			
Week 18 (N= 70, 68, 68, 75, 66)	-0.55 (± 2.168)			
Week 19 (N= 69, 67, 70, 75, 67)	-0.75 (± 2.278)			
Week 20 (N= 68, 67, 69, 72, 67)	-0.67 (± 2.201)			
Week 21 (N= 69, 68, 70, 72, 67)	-0.76 (± 2.332)			
Week 22 (N= 69, 66, 69, 72, 67)	-0.73 (± 2.314)			
Week 23 (N= 70, 67, 70, 71, 67)	-0.61 (± 2.215)			
Week 24 (N= 70, 66, 70, 71, 67)	-0.55 (± 2.224)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Weekly Average of Pruritus Numerical Rating Scale (NRS) From Baseline (Part 2)

End point title	Absolute Change in Weekly Average of Pruritus Numerical Rating Scale (NRS) From Baseline (Part 2)
End point description:	
<p>The pruritus NRS is a simple assessment tool to report the intensity of their pruritus (itch) ranges from 0 to 10 with 0 being 'no itch' and 10 being the 'worst itch imaginable'.</p> <p>The Full Analysis Set (FAS2) for Part 2 included all re-randomized participants at Week 24. Only those participants with data available at specified timepoints were reported.</p>	
End point type	Secondary
End point timeframe:	
Baseline to Weeks 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, and 52	

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 26, 11, 33, 6, 33, 16)	-3.63 (± 2.380)	-2.83 (± 2.909)	-4.00 (± 2.711)	-2.25 (± 2.861)
Week 25 (N= 13, 34, 12, 25, 12, 31, 6, 33, 15)	-3.83 (± 2.353)	-2.73 (± 2.973)	-4.08 (± 2.726)	-2.42 (± 2.895)
Week 26 (N= 13, 33, 12, 25, 11, 30, 7, 33, 15)	-3.82 (± 2.442)	-2.71 (± 2.891)	-3.75 (± 2.654)	-2.33 (± 3.096)
Week 27 (N= 13, 33, 12, 24, 11, 30, 7, 33, 14)	-3.84 (± 2.444)	-2.58 (± 2.819)	-3.65 (± 2.619)	-2.28 (± 2.994)
Week 28 (N= 13, 33, 12, 26, 11, 31, 7, 32, 14)	-3.86 (± 2.432)	-2.56 (± 2.892)	-3.59 (± 2.575)	-2.29 (± 2.782)
Week 29 (N= 13, 32, 11, 25, 12, 31, 7, 31, 14)	-3.73 (± 2.612)	-2.51 (± 2.874)	-3.81 (± 2.425)	-1.85 (± 2.733)
Week 30 (N= 13, 34, 11, 27, 12, 31, 6, 32, 13)	-3.32 (± 2.564)	-2.78 (± 3.030)	-3.76 (± 2.394)	-2.07 (± 2.564)
Week 31 (N= 13, 32, 11, 26, 12, 31, 6, 33, 15)	-3.41 (± 2.580)	-2.74 (± 3.213)	-3.73 (± 2.431)	-1.71 (± 2.980)
Week 32 (N= 13, 34, 11, 25, 12, 32, 7, 33, 14)	-3.43 (± 2.607)	-2.56 (± 3.098)	-3.13 (± 2.818)	-1.51 (± 2.736)
Week 33 (N= 13, 34, 11, 26, 12, 32, 7, 33, 14)	-3.60 (± 2.722)	-2.49 (± 3.220)	-3.06 (± 2.755)	-1.85 (± 2.867)
Week 34 (N= 13, 33, 11, 26, 12, 31, 7, 32, 13)	-3.49 (± 2.644)	-2.26 (± 3.114)	-3.32 (± 2.732)	-1.30 (± 2.792)
Week 35 (N= 13, 34, 11, 27, 12, 32, 7, 31, 14)	-3.47 (± 2.712)	-2.51 (± 3.219)	-3.09 (± 2.600)	-1.42 (± 2.685)
Week 36 (N= 13, 34, 11, 27, 12, 32, 7, 30, 14)	-3.48 (± 2.752)	-2.47 (± 3.262)	-2.81 (± 2.693)	-1.64 (± 2.670)
Week 37 (N= 13, 34, 11, 27, 12, 31, 7, 30, 14)	-3.44 (± 2.726)	-2.53 (± 3.244)	-2.50 (± 2.523)	-1.85 (± 2.758)
Week 38 (N= 13, 33, 11, 26, 12, 32, 7, 30, 13)	-3.31 (± 3.182)	-2.33 (± 3.159)	-2.06 (± 2.464)	-1.74 (± 2.803)
Week 39 (N= 13, 32, 11, 26, 12, 32, 7, 29, 14)	-3.34 (± 3.206)	-2.35 (± 3.212)	-2.52 (± 2.462)	-1.81 (± 2.792)
Week 40 (N= 13, 32, 10, 26, 12, 32, 6, 29, 14)	-3.29 (± 3.245)	-2.26 (± 3.208)	-2.11 (± 2.064)	-1.74 (± 2.697)
Week 41 (N= 13, 32, 9, 26, 12, 31, 7, 29, 13)	-3.25 (± 3.188)	-2.26 (± 3.213)	-1.82 (± 1.991)	-1.97 (± 2.774)
Week 42 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-3.21 (± 3.218)	-2.28 (± 3.307)	-2.53 (± 2.603)	-1.91 (± 2.835)
Week 43 (N= 13, 32, 11, 27, 12, 32, 7, 30, 12)	-3.30 (± 3.246)	-2.27 (± 3.158)	-2.53 (± 2.523)	-1.74 (± 2.821)
Week 44 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-3.34 (± 3.276)	-2.31 (± 3.196)	-2.37 (± 2.349)	-1.79 (± 2.690)
Week 45 (N= 12, 32, 10, 27, 12, 31, 7, 30, 13)	-3.63 (± 3.034)	-2.41 (± 3.267)	-1.97 (± 2.110)	-1.87 (± 2.745)
Week 46 (N= 12, 32, 10, 27, 12, 31, 7, 29, 11)	-3.29 (± 3.359)	-2.46 (± 3.219)	-2.61 (± 2.550)	-1.84 (± 2.679)

Week 47 (N= 12, 32, 9, 27, 12, 31, 7, 30, 13)	-3.17 (± 3.283)	-2.31 (± 3.183)	-1.95 (± 2.320)	-1.84 (± 2.796)
Week 48 (N= 12, 32, 9, 27, 12, 30, 7, 29, 13)	-2.82 (± 3.247)	-2.43 (± 3.202)	-2.36 (± 2.366)	-1.84 (± 2.761)
Week 49 (N= 12, 31, 10, 27, 12, 30, 7, 30, 12)	-2.80 (± 3.230)	-2.27 (± 3.139)	-2.66 (± 2.610)	-2.02 (± 2.909)
Week 50 (N= 12, 31, 10, 27, 12, 29, 7, 30, 12)	-2.78 (± 3.223)	-2.23 (± 3.218)	-2.44 (± 2.699)	-1.90 (± 2.913)
Week 51 (N= 12, 30, 10, 27, 11, 29, 7, 30, 12)	-2.67 (± 3.188)	-2.42 (± 3.317)	-2.39 (± 2.399)	-1.80 (± 2.860)
Week 52 (N= 12, 30, 9, 27, 12, 29, 7, 30, 12)	-2.70 (± 3.119)	-2.17 (± 3.152)	-2.53 (± 2.917)	-1.84 (± 2.779)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 26, 11, 33, 6, 33, 16)	-4.34 (± 2.169)	-2.92 (± 2.539)	-4.63 (± 1.822)	-2.82 (± 2.571)
Week 25 (N= 13, 34, 12, 25, 12, 31, 6, 33, 15)	-4.12 (± 2.413)	-2.81 (± 2.405)	-4.92 (± 1.863)	-2.64 (± 2.577)
Week 26 (N= 13, 33, 12, 25, 11, 30, 7, 33, 15)	-3.83 (± 2.428)	-2.56 (± 2.400)	-4.56 (± 1.903)	-2.70 (± 2.634)
Week 27 (N= 13, 33, 12, 24, 11, 30, 7, 33, 14)	-4.09 (± 2.567)	-2.84 (± 2.467)	-4.51 (± 1.790)	-2.57 (± 2.748)
Week 28 (N= 13, 33, 12, 26, 11, 31, 7, 32, 14)	-4.02 (± 2.525)	-3.01 (± 2.504)	-4.38 (± 1.827)	-2.75 (± 2.753)
Week 29 (N= 13, 32, 11, 25, 12, 31, 7, 31, 14)	-4.16 (± 2.387)	-2.99 (± 2.591)	-4.50 (± 2.035)	-2.64 (± 2.695)
Week 30 (N= 13, 34, 11, 27, 12, 31, 6, 32, 13)	-4.44 (± 2.526)	-2.68 (± 2.490)	-3.73 (± 2.125)	-2.59 (± 2.653)
Week 31 (N= 13, 32, 11, 26, 12, 31, 6, 33, 15)	-4.18 (± 2.428)	-2.81 (± 2.662)	-4.02 (± 2.280)	-2.78 (± 2.691)
Week 32 (N= 13, 34, 11, 25, 12, 32, 7, 33, 14)	-4.27 (± 2.261)	-2.86 (± 2.617)	-4.40 (± 2.170)	-2.68 (± 2.674)
Week 33 (N= 13, 34, 11, 26, 12, 32, 7, 33, 14)	-4.32 (± 2.316)	-2.83 (± 2.579)	-4.14 (± 1.843)	-2.66 (± 2.705)
Week 34 (N= 13, 33, 11, 26, 12, 31, 7, 32, 13)	-4.43 (± 2.297)	-2.84 (± 2.508)	-3.97 (± 1.948)	-2.58 (± 2.665)
Week 35 (N= 13, 34, 11, 27, 12, 32, 7, 31, 14)	-4.60 (± 2.497)	-3.01 (± 2.529)	-4.55 (± 2.055)	-2.65 (± 2.674)
Week 36 (N= 13, 34, 11, 27, 12, 32, 7, 30, 14)	-4.67 (± 2.468)	-2.90 (± 2.527)	-4.14 (± 1.845)	-2.39 (± 2.626)
Week 37 (N= 13, 34, 11, 27, 12, 31, 7, 30, 14)	-4.51 (± 2.429)	-3.11 (± 2.508)	-4.49 (± 1.992)	-2.33 (± 2.564)
Week 38 (N= 13, 33, 11, 26, 12, 32, 7, 30, 13)	-4.57 (± 2.505)	-3.16 (± 2.672)	-4.52 (± 2.046)	-2.37 (± 2.548)
Week 39 (N= 13, 32, 11, 26, 12, 32, 7, 29, 14)	-4.24 (± 2.451)	-3.07 (± 2.548)	-4.66 (± 2.070)	-2.27 (± 2.605)
Week 40 (N= 13, 32, 10, 26, 12, 32, 6, 29, 14)	-4.24 (± 2.419)	-2.92 (± 2.574)	-2.98 (± 1.946)	-2.38 (± 2.659)

Week 41 (N= 13, 32, 9, 26, 12, 31, 7, 29, 13)	-4.56 (± 2.344)	-2.67 (± 2.798)	-3.73 (± 2.142)	-2.41 (± 2.697)
Week 42 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-4.67 (± 2.494)	-2.92 (± 2.876)	-3.78 (± 2.183)	-2.24 (± 2.655)
Week 43 (N= 13, 32, 11, 27, 12, 32, 7, 30, 12)	-4.64 (± 2.864)	-2.82 (± 2.612)	-3.70 (± 2.063)	-2.22 (± 2.736)
Week 44 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-4.83 (± 2.484)	-2.81 (± 2.693)	-3.51 (± 2.084)	-2.21 (± 2.656)
Week 45 (N= 12, 32, 10, 27, 12, 31, 7, 30, 13)	-4.68 (± 2.637)	-2.62 (± 2.636)	-3.58 (± 1.992)	-2.23 (± 2.678)
Week 46 (N= 12, 32, 10, 27, 12, 31, 7, 29, 11)	-4.41 (± 2.864)	-2.33 (± 2.614)	-3.78 (± 2.146)	-2.28 (± 2.713)
Week 47 (N= 12, 32, 9, 27, 12, 31, 7, 30, 13)	-4.46 (± 2.830)	-2.30 (± 2.731)	-3.66 (± 2.139)	-2.38 (± 2.645)
Week 48 (N= 12, 32, 9, 27, 12, 30, 7, 29, 13)	-4.64 (± 2.892)	-2.04 (± 2.636)	-3.96 (± 2.251)	-2.31 (± 2.731)
Week 49 (N= 12, 31, 10, 27, 12, 30, 7, 30, 12)	-4.68 (± 2.893)	-2.02 (± 2.625)	-3.65 (± 1.938)	-2.46 (± 2.847)
Week 50 (N= 12, 31, 10, 27, 12, 29, 7, 30, 12)	-4.56 (± 2.923)	-1.87 (± 2.596)	-3.78 (± 2.092)	-2.35 (± 2.788)
Week 51 (N= 12, 30, 10, 27, 11, 29, 7, 30, 12)	-4.64 (± 3.094)	-1.89 (± 2.692)	-3.66 (± 2.014)	-2.40 (± 2.777)
Week 52 (N= 12, 30, 9, 27, 12, 29, 7, 30, 12)	-4.74 (± 2.909)	-1.84 (± 2.929)	-3.86 (± 2.135)	-2.33 (± 2.811)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 26, 11, 33, 6, 33, 16)	-1.95 (± 3.083)			
Week 25 (N= 13, 34, 12, 25, 12, 31, 6, 33, 15)	-2.08 (± 3.177)			
Week 26 (N= 13, 33, 12, 25, 11, 30, 7, 33, 15)	-1.93 (± 3.202)			
Week 27 (N= 13, 33, 12, 24, 11, 30, 7, 33, 14)	-2.04 (± 3.351)			
Week 28 (N= 13, 33, 12, 26, 11, 31, 7, 32, 14)	-1.89 (± 3.459)			
Week 29 (N= 13, 32, 11, 25, 12, 31, 7, 31, 14)	-1.81 (± 3.386)			
Week 30 (N= 13, 34, 11, 27, 12, 31, 6, 32, 13)	-1.80 (± 3.445)			
Week 31 (N= 13, 32, 11, 26, 12, 31, 6, 33, 15)	-1.46 (± 3.132)			
Week 32 (N= 13, 34, 11, 25, 12, 32, 7, 33, 14)	-1.54 (± 3.221)			
Week 33 (N= 13, 34, 11, 26, 12, 32, 7, 33, 14)	-1.45 (± 3.332)			
Week 34 (N= 13, 33, 11, 26, 12, 31, 7, 32, 13)	-1.86 (± 3.578)			
Week 35 (N= 13, 34, 11, 27, 12, 32, 7, 31, 14)	-1.86 (± 3.390)			

Week 36 (N= 13, 34, 11, 27, 12, 32, 7, 30, 14)	-1.56 (± 3.318)			
Week 37 (N= 13, 34, 11, 27, 12, 31, 7, 30, 14)	-1.58 (± 3.328)			
Week 38 (N= 13, 33, 11, 26, 12, 32, 7, 30, 13)	-1.64 (± 3.449)			
Week 39 (N= 13, 32, 11, 26, 12, 32, 7, 29, 14)	-1.78 (± 3.350)			
Week 40 (N= 13, 32, 10, 26, 12, 32, 6, 29, 14)	-1.67 (± 3.413)			
Week 41 (N= 13, 32, 9, 26, 12, 31, 7, 29, 13)	-1.64 (± 3.856)			
Week 42 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-2.01 (± 3.719)			
Week 43 (N= 13, 32, 11, 27, 12, 32, 7, 30, 12)	-2.31 (± 3.823)			
Week 44 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-2.01 (± 3.730)			
Week 45 (N= 12, 32, 10, 27, 12, 31, 7, 30, 13)	-1.87 (± 3.752)			
Week 46 (N= 12, 32, 10, 27, 12, 31, 7, 29, 11)	-1.99 (± 4.071)			
Week 47 (N= 12, 32, 9, 27, 12, 31, 7, 30, 13)	-1.78 (± 3.762)			
Week 48 (N= 12, 32, 9, 27, 12, 30, 7, 29, 13)	-2.05 (± 3.716)			
Week 49 (N= 12, 31, 10, 27, 12, 30, 7, 30, 12)	-2.06 (± 3.875)			
Week 50 (N= 12, 31, 10, 27, 12, 29, 7, 30, 12)	-2.16 (± 3.870)			
Week 51 (N= 12, 30, 10, 27, 11, 29, 7, 30, 12)	-2.12 (± 3.883)			
Week 52 (N= 12, 30, 9, 27, 12, 29, 7, 30, 12)	-2.12 (± 3.904)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change in Weekly Average of Pruritus Numerical Rating Scale (NRS) From Baseline (Part 1)

End point title	Percent Change in Weekly Average of Pruritus Numerical Rating Scale (NRS) From Baseline (Part 1)
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End point description:

The pruritus NRS is a simple assessment tool to report the intensity of their pruritus (itch) ranges from 0 to 10 with 0 being 'no itch' and 10 being the 'worst itch imaginable'.

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 and 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: Percentage of change				
arithmetic mean (standard deviation)				
Week 1 (N= 74, 77, 77, 77, 77)	-6.26 (± 16.312)	-7.25 (± 13.575)	-6.18 (± 13.809)	-6.05 (± 13.049)
Week 2 (N= 75, 77, 76, 76, 77)	-7.50 (± 20.644)	-10.37 (± 19.307)	-9.86 (± 14.734)	-11.20 (± 18.124)
Week 3 (N= 75, 77, 77, 77, 76)	-11.08 (± 24.712)	-12.11 (± 18.977)	-14.11 (± 17.784)	-12.08 (± 22.244)
Week 4 (N= 75, 76, 76, 77, 77)	-12.16 (± 25.287)	-16.73 (± 22.997)	-18.37 (± 19.932)	-14.95 (± 24.356)
Week 5 (N= 75, 75, 75, 77, 74)	-12.58 (± 27.613)	-18.64 (± 23.725)	-19.20 (± 21.900)	-20.17 (± 25.112)
Week 6 (N= 74, 73, 75, 76, 75)	-13.73 (± 25.374)	-17.59 (± 25.814)	-18.68 (± 22.790)	-21.29 (± 28.179)
Week 7 (N= 73, 72, 74, 76, 73)	-15.89 (± 28.992)	-20.18 (± 25.476)	-21.18 (± 23.816)	-24.03 (± 27.650)
Week 8 (N= 73, 72, 73, 75, 73)	-18.41 (± 31.375)	-19.99 (± 24.992)	-21.14 (± 24.981)	-26.10 (± 27.810)
Week 9 (N= 74, 73, 74, 75, 70)	-18.83 (± 32.003)	-20.36 (± 25.407)	-25.45 (± 24.895)	-29.18 (± 27.455)
Week 10 (N= 72, 73, 72, 74, 69)	-21.19 (± 32.110)	-22.53 (± 25.815)	-24.46 (± 28.280)	-29.43 (± 28.109)
Week 11 (N= 73, 70, 73, 74, 68)	-21.93 (± 31.966)	-22.37 (± 26.321)	-27.67 (± 28.079)	-31.26 (± 29.641)
Week 12 (N= 72, 69, 71, 73, 68)	-22.59 (± 32.927)	-22.05 (± 28.445)	-26.52 (± 28.426)	-31.23 (± 30.323)
Week 13 (N= 72, 71, 71, 73, 70)	-23.88 (± 33.561)	-24.71 (± 30.761)	-28.18 (± 29.401)	-31.36 (± 31.724)
Week 14 (N= 72, 70, 70, 75, 67)	-23.87 (± 34.926)	-26.45 (± 32.870)	-29.19 (± 30.904)	-32.57 (± 31.719)
Week 15 (N= 70, 69, 71, 74, 67)	-24.40 (± 34.899)	-27.46 (± 33.838)	-28.87 (± 31.207)	-32.01 (± 30.980)
Week 16 (N= 72, 68, 71, 75, 66)	-26.85 (± 36.332)	-27.92 (± 33.619)	-30.75 (± 30.460)	-31.97 (± 31.194)
Week 17 (N= 70, 68, 71, 75, 67)	-27.81 (± 35.262)	-29.27 (± 33.331)	-29.68 (± 31.753)	-32.60 (± 31.851)
Week 18 (N= 70, 68, 68, 75, 66)	-28.78 (± 36.738)	-29.49 (± 34.514)	-29.89 (± 31.200)	-32.50 (± 32.096)
Week 19 (N= 69, 67, 70, 75, 67)	-28.98 (± 36.372)	-29.78 (± 35.087)	-29.83 (± 31.632)	-32.77 (± 33.698)
Week 20 (N= 68, 67, 69, 72, 67)	-30.61 (± 37.215)	-29.30 (± 34.365)	-29.48 (± 32.361)	-31.85 (± 32.767)
Week 21 (N= 69, 68, 70, 72, 67)	-30.40 (± 36.928)	-29.63 (± 34.869)	-31.61 (± 32.551)	-33.20 (± 33.098)
Week 22 (N= 69, 66, 69, 72, 67)	-31.81 (± 38.100)	-30.35 (± 36.881)	-31.15 (± 33.763)	-33.28 (± 32.108)
Week 23 (N= 70, 67, 70, 71, 67)	-34.26 (± 38.693)	-30.30 (± 35.236)	-30.52 (± 35.354)	-35.25 (± 33.102)
Week 24 (N= 70, 66, 70, 71, 67)	-34.70 (± 38.656)	-30.44 (± 36.696)	-30.64 (± 36.647)	-33.26 (± 32.433)

End point values	Placebo (Part			
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	1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: Percentage of change				
arithmetic mean (standard deviation)				
Week 1 (N= 74, 77, 77, 77, 77)	-3.70 (± 16.432)			
Week 2 (N= 75, 77, 76, 76, 77)	-5.63 (± 15.340)			
Week 3 (N= 75, 77, 77, 77, 76)	-7.89 (± 22.004)			
Week 4 (N= 75, 76, 76, 77, 77)	-9.83 (± 24.266)			
Week 5 (N= 75, 75, 75, 77, 74)	-10.14 (± 29.071)			
Week 6 (N= 74, 73, 75, 76, 75)	-12.43 (± 27.184)			
Week 7 (N= 73, 72, 74, 76, 73)	-10.18 (± 28.308)			
Week 8 (N= 73, 72, 73, 75, 73)	-10.51 (± 29.803)			
Week 9 (N= 74, 73, 74, 75, 70)	-13.34 (± 32.225)			
Week 10 (N= 72, 73, 72, 74, 69)	-12.99 (± 33.194)			
Week 11 (N= 73, 70, 73, 74, 68)	-12.73 (± 31.638)			
Week 12 (N= 72, 69, 71, 73, 68)	-10.62 (± 32.707)			
Week 13 (N= 72, 71, 71, 73, 70)	-10.05 (± 32.122)			
Week 14 (N= 72, 70, 70, 75, 67)	-7.60 (± 31.351)			
Week 15 (N= 70, 69, 71, 74, 67)	-6.87 (± 29.583)			
Week 16 (N= 72, 68, 71, 75, 66)	-6.62 (± 30.591)			
Week 17 (N= 70, 68, 71, 75, 67)	-7.46 (± 31.529)			
Week 18 (N= 70, 68, 68, 75, 66)	-6.37 (± 31.752)			
Week 19 (N= 69, 67, 70, 75, 67)	-9.50 (± 33.411)			
Week 20 (N= 68, 67, 69, 72, 67)	-8.56 (± 32.725)			
Week 21 (N= 69, 68, 70, 72, 67)	-9.71 (± 34.201)			
Week 22 (N= 69, 66, 69, 72, 67)	-9.36 (± 34.161)			
Week 23 (N= 70, 67, 70, 71, 67)	-7.23 (± 32.486)			
Week 24 (N= 70, 66, 70, 71, 67)	-6.66 (± 32.550)			

Statistical analyses

Secondary: Percent Change in Weekly Average of Pruritus Numerical Rating Scale (NRS) From Baseline (Part 2)

End point title	Percent Change in Weekly Average of Pruritus Numerical Rating Scale (NRS) From Baseline (Part 2)
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End point description:

The pruritus NRS is a simple assessment tool to report the intensity of their pruritus (itch) ranges from 0 to 10 with 0 being 'no itch' and 10 being the 'worst itch imaginable'.

The Full Analysis Set (FAS2) for Part 2 included all re-randomized participants at Week 24. Only those participants with data available at specified timepoints were reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 26, 11, 33, 6, 33, 16)	-49.61 (± 33.036)	-38.71 (± 44.259)	-52.36 (± 33.258)	-29.76 (± 40.611)
Week 25 (N= 13, 34, 12, 25, 12, 31, 6, 33, 15)	-52.15 (± 31.579)	-36.78 (± 45.402)	-53.26 (± 33.810)	-31.69 (± 40.647)
Week 26 (N= 13, 33, 12, 25, 11, 30, 7, 33, 15)	-51.62 (± 32.197)	-36.84 (± 44.342)	-48.88 (± 32.071)	-30.68 (± 42.883)
Week 27 (N= 13, 33, 12, 24, 11, 30, 7, 33, 14)	-52.09 (± 32.613)	-35.34 (± 44.056)	-47.36 (± 30.909)	-29.42 (± 40.379)
Week 28 (N= 13, 33, 12, 26, 11, 31, 7, 32, 14)	-52.36 (± 32.642)	-34.80 (± 45.063)	-47.19 (± 31.551)	-30.58 (± 38.398)
Week 29 (N= 13, 32, 11, 25, 12, 31, 7, 31, 14)	-50.48 (± 35.634)	-34.13 (± 44.735)	-50.29 (± 29.286)	-24.35 (± 38.746)
Week 30 (N= 13, 34, 11, 27, 12, 31, 6, 32, 13)	-44.79 (± 34.219)	-37.91 (± 46.288)	-49.35 (± 28.435)	-28.00 (± 35.916)
Week 31 (N= 13, 32, 11, 26, 12, 31, 6, 33, 15)	-46.03 (± 34.355)	-37.18 (± 49.311)	-49.01 (± 28.581)	-21.78 (± 41.439)
Week 32 (N= 13, 34, 11, 25, 12, 32, 7, 33, 14)	-46.40 (± 35.233)	-34.68 (± 47.719)	-40.69 (± 34.523)	-19.61 (± 37.935)
Week 33 (N= 13, 34, 11, 26, 12, 32, 7, 33, 14)	-48.66 (± 36.625)	-33.52 (± 48.881)	-39.31 (± 33.036)	-24.61 (± 40.379)
Week 34 (N= 13, 33, 11, 26, 12, 31, 7, 32, 13)	-47.09 (± 35.098)	-30.56 (± 48.227)	-43.33 (± 34.277)	-17.18 (± 39.855)
Week 35 (N= 13, 34, 11, 27, 12, 32, 7, 31, 14)	-46.67 (± 36.047)	-33.99 (± 48.416)	-40.21 (± 32.239)	-18.51 (± 37.670)
Week 36 (N= 13, 34, 11, 27, 12, 32, 7, 30, 14)	-46.63 (± 36.326)	-33.43 (± 48.720)	-36.23 (± 33.872)	-22.43 (± 37.322)
Week 37 (N= 13, 34, 11, 27, 12, 31, 7, 30, 14)	-45.95 (± 35.161)	-34.42 (± 48.542)	-32.60 (± 31.909)	-25.63 (± 39.489)
Week 38 (N= 13, 33, 11, 26, 12, 32, 7, 30, 13)	-43.12 (± 42.814)	-31.62 (± 47.534)	-26.80 (± 31.244)	-24.20 (± 40.063)

Week 39 (N= 13, 32, 11, 26, 12, 32, 7, 29, 14)	-43.54 (± 42.937)	-31.75 (± 48.313)	-32.75 (± 31.185)	-25.49 (± 40.126)
Week 40 (N= 13, 32, 10, 26, 12, 32, 6, 29, 14)	-42.94 (± 43.748)	-30.52 (± 48.657)	-27.37 (± 25.233)	-24.24 (± 38.972)
Week 41 (N= 13, 32, 9, 26, 12, 31, 7, 29, 13)	-42.33 (± 43.065)	-30.85 (± 48.900)	-22.99 (± 23.218)	-27.38 (± 39.966)
Week 42 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-41.68 (± 42.874)	-30.76 (± 50.332)	-34.23 (± 35.319)	-26.33 (± 40.513)
Week 43 (N= 13, 32, 11, 27, 12, 32, 7, 30, 12)	-42.86 (± 43.495)	-30.51 (± 48.200)	-33.86 (± 33.053)	-23.93 (± 40.455)
Week 44 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-43.47 (± 44.000)	-31.71 (± 49.607)	-31.76 (± 30.960)	-24.67 (± 37.725)
Week 45 (N= 12, 32, 10, 27, 12, 31, 7, 30, 13)	-47.27 (± 40.996)	-33.33 (± 50.319)	-25.91 (± 26.492)	-25.91 (± 38.680)
Week 46 (N= 12, 32, 10, 27, 12, 31, 7, 29, 11)	-42.11 (± 45.119)	-33.68 (± 49.356)	-34.27 (± 33.932)	-25.58 (± 38.019)
Week 47 (N= 12, 32, 9, 27, 12, 31, 7, 30, 13)	-40.77 (± 44.580)	-31.88 (± 48.778)	-25.60 (± 30.211)	-25.44 (± 39.798)
Week 48 (N= 12, 32, 9, 27, 12, 30, 7, 29, 13)	-36.53 (± 44.443)	-33.50 (± 48.912)	-30.33 (± 30.351)	-25.04 (± 38.230)
Week 49 (N= 12, 31, 10, 27, 12, 30, 7, 30, 12)	-36.53 (± 44.233)	-31.23 (± 48.493)	-34.64 (± 34.631)	-28.21 (± 41.352)
Week 50 (N= 12, 31, 10, 27, 12, 29, 7, 30, 12)	-36.14 (± 44.279)	-31.62 (± 50.758)	-32.01 (± 36.290)	-26.10 (± 40.637)
Week 51 (N= 12, 30, 10, 27, 11, 29, 7, 30, 12)	-34.31 (± 43.008)	-34.07 (± 51.575)	-30.83 (± 31.211)	-24.47 (± 39.779)
Week 52 (N= 12, 30, 9, 27, 12, 29, 7, 30, 12)	-35.06 (± 42.961)	-30.54 (± 49.791)	-33.29 (± 38.191)	-25.37 (± 39.165)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 26, 11, 33, 6, 33, 16)	-56.60 (± 24.568)	-42.27 (± 36.685)	-59.49 (± 22.140)	-38.95 (± 34.963)
Week 25 (N= 13, 34, 12, 25, 12, 31, 6, 33, 15)	-54.31 (± 29.223)	-41.26 (± 34.643)	-63.84 (± 23.417)	-37.04 (± 36.046)
Week 26 (N= 13, 33, 12, 25, 11, 30, 7, 33, 15)	-50.31 (± 29.134)	-38.14 (± 35.393)	-57.52 (± 22.280)	-37.71 (± 37.451)
Week 27 (N= 13, 33, 12, 24, 11, 30, 7, 33, 14)	-53.62 (± 30.255)	-42.65 (± 36.665)	-57.00 (± 20.810)	-35.32 (± 38.963)
Week 28 (N= 13, 33, 12, 26, 11, 31, 7, 32, 14)	-53.08 (± 30.684)	-44.86 (± 36.493)	-56.28 (± 24.247)	-38.37 (± 38.703)
Week 29 (N= 13, 32, 11, 25, 12, 31, 7, 31, 14)	-54.93 (± 28.705)	-44.31 (± 37.579)	-56.79 (± 23.453)	-36.46 (± 38.211)
Week 30 (N= 13, 34, 11, 27, 12, 31, 6, 32, 13)	-58.70 (± 30.600)	-40.30 (± 37.098)	-48.05 (± 24.892)	-36.03 (± 38.742)
Week 31 (N= 13, 32, 11, 26, 12, 31, 6, 33, 15)	-55.77 (± 30.420)	-42.26 (± 39.161)	-52.67 (± 29.311)	-39.45 (± 38.697)
Week 32 (N= 13, 34, 11, 25, 12, 32, 7, 33, 14)	-57.32 (± 29.140)	-42.64 (± 38.113)	-56.51 (± 27.668)	-37.63 (± 38.453)

Week 33 (N= 13, 34, 11, 26, 12, 32, 7, 33, 14)	-57.76 (± 29.406)	-42.45 (± 38.100)	-52.89 (± 22.337)	-37.50 (± 39.368)
Week 34 (N= 13, 33, 11, 26, 12, 31, 7, 32, 13)	-59.41 (± 29.414)	-42.96 (± 37.718)	-50.34 (± 22.937)	-35.63 (± 37.586)
Week 35 (N= 13, 34, 11, 27, 12, 32, 7, 31, 14)	-61.70 (± 32.381)	-44.99 (± 37.080)	-58.12 (± 24.772)	-36.74 (± 37.592)
Week 36 (N= 13, 34, 11, 27, 12, 32, 7, 30, 14)	-62.54 (± 31.831)	-43.37 (± 37.251)	-52.78 (± 22.120)	-33.66 (± 38.520)
Week 37 (N= 13, 34, 11, 27, 12, 31, 7, 30, 14)	-60.49 (± 31.510)	-46.52 (± 37.336)	-58.05 (± 27.565)	-33.22 (± 38.367)
Week 38 (N= 13, 33, 11, 26, 12, 32, 7, 30, 13)	-60.83 (± 31.559)	-47.17 (± 39.147)	-58.43 (± 27.410)	-33.72 (± 37.516)
Week 39 (N= 13, 32, 11, 26, 12, 32, 7, 29, 14)	-56.79 (± 31.763)	-46.10 (± 38.082)	-59.36 (± 25.162)	-32.70 (± 38.945)
Week 40 (N= 13, 32, 10, 26, 12, 32, 6, 29, 14)	-56.78 (± 31.397)	-43.62 (± 38.048)	-38.57 (± 22.074)	-34.20 (± 39.168)
Week 41 (N= 13, 32, 9, 26, 12, 31, 7, 29, 13)	-61.18 (± 30.487)	-39.66 (± 42.054)	-47.95 (± 26.092)	-34.51 (± 40.123)
Week 42 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-62.53 (± 32.149)	-42.91 (± 42.866)	-49.33 (± 29.448)	-32.01 (± 39.405)
Week 43 (N= 13, 32, 11, 27, 12, 32, 7, 30, 12)	-62.27 (± 36.647)	-41.66 (± 38.115)	-48.09 (± 26.148)	-31.34 (± 41.919)
Week 44 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-64.61 (± 31.787)	-42.36 (± 40.085)	-46.04 (± 28.399)	-31.28 (± 40.103)
Week 45 (N= 12, 32, 10, 27, 12, 31, 7, 30, 13)	-61.59 (± 33.745)	-39.63 (± 39.211)	-47.19 (± 28.645)	-31.41 (± 39.716)
Week 46 (N= 12, 32, 10, 27, 12, 31, 7, 29, 11)	-58.81 (± 35.801)	-34.77 (± 38.757)	-49.76 (± 30.190)	-31.98 (± 39.640)
Week 47 (N= 12, 32, 9, 27, 12, 31, 7, 30, 13)	-59.01 (± 35.211)	-33.49 (± 39.386)	-48.45 (± 30.519)	-33.71 (± 38.282)
Week 48 (N= 12, 32, 9, 27, 12, 30, 7, 29, 13)	-61.01 (± 35.650)	-29.89 (± 38.681)	-51.75 (± 30.214)	-33.16 (± 40.239)
Week 49 (N= 12, 31, 10, 27, 12, 30, 7, 30, 12)	-61.21 (± 35.897)	-29.37 (± 38.374)	-48.17 (± 27.760)	-34.32 (± 41.018)
Week 50 (N= 12, 31, 10, 27, 12, 29, 7, 30, 12)	-59.59 (± 36.330)	-27.45 (± 38.441)	-50.18 (± 30.773)	-32.86 (± 40.330)
Week 51 (N= 12, 30, 10, 27, 11, 29, 7, 30, 12)	-60.72 (± 38.664)	-27.10 (± 39.790)	-48.66 (± 29.191)	-33.72 (± 40.790)
Week 52 (N= 12, 30, 9, 27, 12, 29, 7, 30, 12)	-61.83 (± 35.861)	-25.94 (± 43.683)	-50.89 (± 29.752)	-32.36 (± 40.612)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 26, 11, 33, 6, 33, 16)	-29.09 (± 44.653)			
Week 25 (N= 13, 34, 12, 25, 12, 31, 6, 33, 15)	-30.81 (± 46.001)			
Week 26 (N= 13, 33, 12, 25, 11, 30, 7, 33, 15)	-28.48 (± 46.252)			
Week 27 (N= 13, 33, 12, 24, 11, 30, 7, 33, 14)	-29.92 (± 48.506)			

Week 28 (N= 13, 33, 12, 26, 11, 31, 7, 32, 14)	-27.74 (± 49.936)			
Week 29 (N= 13, 32, 11, 25, 12, 31, 7, 31, 14)	-26.40 (± 48.994)			
Week 30 (N= 13, 34, 11, 27, 12, 31, 6, 32, 13)	-26.58 (± 49.832)			
Week 31 (N= 13, 32, 11, 26, 12, 31, 6, 33, 15)	-21.51 (± 44.331)			
Week 32 (N= 13, 34, 11, 25, 12, 32, 7, 33, 14)	-22.64 (± 46.122)			
Week 33 (N= 13, 34, 11, 26, 12, 32, 7, 33, 14)	-21.49 (± 48.348)			
Week 34 (N= 13, 33, 11, 26, 12, 31, 7, 32, 13)	-27.22 (± 51.629)			
Week 35 (N= 13, 34, 11, 27, 12, 32, 7, 31, 14)	-27.11 (± 48.897)			
Week 36 (N= 13, 34, 11, 27, 12, 32, 7, 30, 14)	-22.57 (± 47.897)			
Week 37 (N= 13, 34, 11, 27, 12, 31, 7, 30, 14)	-22.63 (± 48.038)			
Week 38 (N= 13, 33, 11, 26, 12, 32, 7, 30, 13)	-24.07 (± 49.645)			
Week 39 (N= 13, 32, 11, 26, 12, 32, 7, 29, 14)	-25.98 (± 48.229)			
Week 40 (N= 13, 32, 10, 26, 12, 32, 6, 29, 14)	-24.22 (± 49.044)			
Week 41 (N= 13, 32, 9, 26, 12, 31, 7, 29, 13)	-24.13 (± 55.219)			
Week 42 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-29.48 (± 53.423)			
Week 43 (N= 13, 32, 11, 27, 12, 32, 7, 30, 12)	-33.70 (± 54.865)			
Week 44 (N= 13, 32, 11, 27, 12, 32, 7, 30, 13)	-29.07 (± 53.672)			
Week 45 (N= 12, 32, 10, 27, 12, 31, 7, 30, 13)	-27.07 (± 54.016)			
Week 46 (N= 12, 32, 10, 27, 12, 31, 7, 29, 11)	-28.89 (± 58.573)			
Week 47 (N= 12, 32, 9, 27, 12, 31, 7, 30, 13)	-25.86 (± 54.094)			
Week 48 (N= 12, 32, 9, 27, 12, 30, 7, 29, 13)	-29.29 (± 53.432)			
Week 49 (N= 12, 31, 10, 27, 12, 30, 7, 30, 12)	-29.80 (± 55.717)			
Week 50 (N= 12, 31, 10, 27, 12, 29, 7, 30, 12)	-31.15 (± 55.571)			
Week 51 (N= 12, 30, 10, 27, 11, 29, 7, 30, 12)	-30.75 (± 55.841)			
Week 52 (N= 12, 30, 9, 27, 12, 29, 7, 30, 12)	-30.50 (± 56.024)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Improvement (Reduction) of Weekly Average of Pruritus NRS (Numerical Rating Scale) ≥ 3 With a Baseline Pruritus NRS ≥ 3 From Baseline (Part 1)

End point title	Percentage of Participants With Improvement (Reduction) of Weekly Average of Pruritus NRS (Numerical Rating Scale) \geq 3 With a Baseline Pruritus NRS \geq 3 From Baseline (Part 1)
End point description: The pruritus NRS is a simple assessment tool to report the intensity of their pruritus (itch) ranges from 0 to 10 with 0 being 'no itch' and 10 being the 'worst itch imaginable'. The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24.	
End point type	Secondary
End point timeframe: Baseline to Weeks 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 and 24	

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	79
Units: percentage of participants				
number (not applicable)				
Week 1	2.6	1.3	1.3	1.3
Week 2	3.9	6.4	1.3	6.3
Week 3	9.1	6.4	10.4	76
Week 4	10.4	14.1	15.6	13.9
Week 5	15.6	15.4	16.9	19.0
Week 6	10.4	19.2	18.2	21.5
Week 7	16.9	23.1	20.8	25.3
Week 8	22.1	17.9	22.1	26.6
Week 9	20.8	19.2	27.3	31.6
Week 10	27.3	23.1	28.6	38.0
Week 11	26.0	23.1	31.2	36.7
Week 12	26.0	20.5	28.6	38.0
Week 13	28.6	26.9	29.9	38.0
Week 14	35.1	29.5	28.6	40.5
Week 15	29.9	28.2	28.6	40.5
Week 16	32.5	33.3	29.9	41.8
Week 17	32.5	30.8	27.3	38.0
Week 18	36.4	33.3	29.9	43.0
Week 19	35.1	32.1	33.8	43.0
Week 20	33.8	30.8	31.2	36.7
Week 21	37.7	32.1	33.8	36.7
Week 22	37.7	30.8	33.8	39.2
Week 23	41.6	35.9	37.7	43.0
Week 24	40.3	30.8	36.4	39.2

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of participants				

number (not applicable)				
Week 1	1.3			
Week 2	2.5			
Week 3	6.3			
Week 4	7.6			
Week 5	11.4			
Week 6	12.7			
Week 7	11.4			
Week 8	15.2			
Week 9	13.9			
Week 10	15.2			
Week 11	13.9			
Week 12	16.5			
Week 13	13.9			
Week 14	13.9			
Week 15	10.1			
Week 16	10.1			
Week 17	13.9			
Week 18	12.7			
Week 19	15.2			
Week 20	10.1			
Week 21	15.2			
Week 22	13.9			
Week 23	12.7			
Week 24	11.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Loss of EASI 50 Incidence Rate Per Patient Year (Part 2)

End point title	Loss of EASI 50 Incidence Rate Per Patient Year (Part 2)
End point description:	
Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. Participants who reached EASI 50 at week 24 and re-randomized participants at Week 24.	
End point type	Secondary
End point timeframe:	
Week 24 to Week 52	

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28

Units: Incidence rate				
number (not applicable)				
Loss of EASI 50 Incidence Rate Per Patient Year	0	0.272	0.188	0.089

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	13	7	35
Units: Incidence rate				
number (not applicable)				
Loss of EASI 50 Incidence Rate Per Patient Year	0.165	0.071	0	0.193

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Incidence rate				
number (not applicable)				
Loss of EASI 50 Incidence Rate Per Patient Year	0.145			

Statistical analyses

No statistical analyses for this end point

Secondary: Loss of EASI 75 Incidence Rate Per Patient Year (Part 2)

End point title	Loss of EASI 75 Incidence Rate Per Patient Year (Part 2)
End point description: Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. Participants who reached EASI 75 at Week 24 and re-randomized participants at Week 24.	
End point type	Secondary
End point timeframe: Week 24 to Week 52	

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: Incidence rate				
number (not applicable)				
Loss of EASI 75 Incidence Rate Per Patient Year	0	0.587	0.375	0.486

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: Incidence rate				
number (not applicable)				
Loss of EASI 75 Incidence Rate Per Patient Year	0.395	0.446	0.351	0.573

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Incidence rate				
number (not applicable)				
Loss of EASI 75 Incidence Rate Per Patient Year	0.646			

Statistical analyses

No statistical analyses for this end point

Secondary: Loss of IGA 0/1 Incidence Rate Per Patient Year (Participants With a Response of 0 or 1 in IGA) (Part 2)

End point title	Loss of IGA 0/1 Incidence Rate Per Patient Year (Participants With a Response of 0 or 1 in IGA) (Part 2)
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End point description:

The IGA is a five-point scale that provides a global clinical assessment of AD severity ranging from 0 to 4, where 0 indicates clear, 2 is mild, 3 is moderate, and 4 indicates severe AD. Participants who had IGA response 0 or 1 at week 24 and re-randomized at Week 24.

End point type	Secondary
End point timeframe:	
Week 24 to Week 68	

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: Incidence rate				
number (not applicable)				
Loss of IGA 0/1 Incidence Rate Per Patient Year	1.267	1.039	0.981	1.930

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: Incidence rate				
number (not applicable)				
Loss of IGA 0/1 Incidence Rate Per Patient Year	1.154	1.045	1.096	1.790

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Incidence rate				
number (not applicable)				
Loss of IGA 0/1 Incidence Rate Per Patient Year	0.244			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum KY1005 Concentration Assessed Throughout the Study (Part 1)

End point title	Serum KY1005 Concentration Assessed Throughout the Study (Part 1) ^[1]
End point description: This analysis was conducted for Part 1 and includes participants who took at least one dose of KY1005. Only those participants with data available at specified timepoints were reported.	
End point type	Secondary
End point timeframe: Baseline and at Weeks 1, 2, 4, 8, 12, 16, 17, 20 and 24	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Serum KY1005 Concentration test is not applicable for Placebo arm.

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	76	77	77
Units: ug/ml				
arithmetic mean (standard deviation)				
Baseline (N= 77, 74, 76, 73)	0.00 (± 0.014)	0.00 (± 0.014)	0.01 (± 0.074)	0.00 (± 0.000)
Week 1 (N= 72, 73, 74, 73)	58.29 (± 24.674)	30.49 (± 18.520)	14.18 (± 5.060)	8.49 (± 3.331)
Week 2 (N= 65, 69, 67, 70)	47.56 (± 17.274)	25.09 (± 9.041)	13.56 (± 3.886)	7.57 (± 2.947)
Week 4 (N= 62, 65, 69, 68)	38.49 (± 22.532)	19.00 (± 7.869)	9.67 (± 3.728)	5.09 (± 2.176)
Week 8 (N= 53, 48, 56, 61)	37.67 (± 15.157)	32.14 (± 16.502)	15.07 (± 6.383)	7.92 (± 3.263)
Week 12 (N= 50, 45, 54, 60)	39.26 (± 33.847)	34.67 (± 15.191)	18.12 (± 8.439)	9.22 (± 4.116)
Week 16 (N= 49, 48, 49, 52)	40.12 (± 28.610)	38.09 (± 13.536)	18.39 (± 7.245)	10.13 (± 4.515)
Week 17 (N= 49, 54, 54, 51)	62.34 (± 28.081)	64.64 (± 24.169)	29.26 (± 11.659)	16.79 (± 6.677)
Week 20 (N= 49, 49, 54, 56)	37.92 (± 14.171)	48.26 (± 30.691)	19.31 (± 7.203)	10.68 (± 3.715)
Week 24 (N= 41, 43, 47, 43)	41.98 (± 23.087)	43.81 (± 17.403)	20.25 (± 10.575)	11.07 (± 3.918)

Statistical analyses

No statistical analyses for this end point

Secondary: Serum KY1005 Concentration Assessed Throughout the Study (Part 2)

End point title	Serum KY1005 Concentration Assessed Throughout the Study (Part 2)
End point description: This analysis was conducted for Part 2 and includes participants who took at least one dose of KY1005. Only those participants with data available at specified timepoints are reported	
End point type	Secondary
End point timeframe: Baseline and at Weeks 24, 25, 28, 32, 36, 40, 44, 48 and 52	

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: ug/ml				
arithmetic mean (standard deviation)				
Week 24 (N= 9, 18, 11, 19, 10, 20, 4, 19)	45.13 (± 15.842)	36.68 (± 17.544)	45.00 (± 14.568)	43.17 (± 19.752)
Week 25 (N= 12, 28, 10, 23, 10, 24, 4, 24)	73.54 (± 30.680)	36.54 (± 20.508)	71.25 (± 16.294)	34.71 (± 14.551)
Week 28 (N= 13, 23, 11, 21, 10, 24, 3, 23)	51.50 (± 25.454)	17.59 (± 9.090)	46.15 (± 15.782)	25.22 (± 10.235)
Week 32 (N= 11, 20, 10, 15, 9, 18, 3, 21)	44.41 (± 11.438)	8.86 (± 5.074)	41.50 (± 13.681)	12.54 (± 5.943)
Week 36 (N= 9, 20, 9, 16, 9, 20, 4, 20)	43.11 (± 18.965)	5.41 (± 3.876)	51.42 (± 18.946)	7.80 (± 4.413)
Week 40 (N= 9, 20, 9, 18, 8, 23, 5, 20)	45.19 (± 19.921)	2.42 (± 1.660)	43.79 (± 15.955)	4.54 (± 2.929)
Week 44 (N= 10, 21, 8, 18, 10, 19, 6, 21)	40.91 (± 12.068)	1.04 (± 0.908)	46.98 (± 24.015)	2.62 (± 2.193)
Week 48 (N= 11, 18, 8, 19, 9, 19, 6, 21)	41.43 (± 14.214)	0.58 (± 0.507)	43.63 (± 22.188)	1.40 (± 1.727)
Week 52 (N= 10, 20, 10, 17, 7, 20, 5, 19)	38.88 (± 11.526)	0.56 (± 1.112)	45.59 (± 22.447)	0.55 (± 0.573)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-Randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-Randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: ug/ml				
arithmetic mean (standard deviation)				
Week 24 (N= 9, 18, 11, 19, 10, 20, 4, 19)	19.03 (± 9.612)	19.48 (± 7.791)	11.60 (± 1.383)	11.10 (± 5.240)
Week 25 (N= 12, 28, 10, 23, 10, 24, 4, 24)	31.07 (± 16.115)	17.57 (± 7.504)	15.90 (± 2.443)	10.36 (± 5.145)
Week 28 (N= 13, 23, 11, 21, 10, 24, 3, 23)	20.12 (± 11.820)	10.03 (± 4.697)	9.56 (± 3.485)	6.66 (± 2.584)
Week 32 (N= 11, 20, 10, 15, 9, 18, 3, 21)	20.99 (± 12.614)	4.57 (± 2.463)	9.40 (± 1.749)	3.32 (± 1.588)
Week 36 (N= 9, 20, 9, 16, 9, 20, 4, 20)	22.28 (± 18.101)	2.85 (± 2.275)	13.38 (± 2.128)	1.77 (± 1.018)
Week 40 (N= 9, 20, 9, 18, 8, 23, 5, 20)	19.09 (± 11.479)	1.68 (± 1.669)	10.95 (± 1.350)	0.96 (± 0.748)
Week 44 (N= 10, 21, 8, 18, 10, 19, 6, 21)	16.43 (± 7.302)	0.82 (± 0.863)	11.25 (± 2.607)	0.57 (± 0.554)

Week 48 (N= 11, 18, 8, 19, 9, 19, 6, 21)	17.80 (± 9.065)	0.42 (± 0.483)	11.12 (± 1.825)	0.25 (± 0.305)
Week 52 (N= 10, 20, 10, 17, 7, 20, 5, 19)	22.60 (± 8.225)	0.19 (± 0.289)	12.03 (± 3.775)	0.11 (± 0.129)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With at Least One Treatment-emergent Adverse Event (TEAE) and Any Serious TEAE (Part 1)

End point title	Percentage of Participants With at Least One Treatment-emergent Adverse Event (TEAE) and Any Serious TEAE (Part 1)
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End point description:

Safety Analysis Part 1: Participants who took at least a dose of study treatment, including placebo up to Week 24. Analysis based on the SAF1 was based on the treatment received, regardless of assigned treatment according to the randomization.

End point type	Secondary
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End point timeframe:

Baseline through Week 24

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	78	77	78
Units: percentage of participants				
number (not applicable)				
Percentage of Participants With at Least One TEAE	66.2	66.7	67.5	67.9
Percentage of Participants With Any Serious TEAE	2.6	0	1.3	6.4

End point values	Placebo (Part 1)			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: percentage of participants				
number (not applicable)				
Percentage of Participants With at Least One TEAE	60.3			
Percentage of Participants With Any Serious TEAE	1.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With at Least One Treatment-emergent Adverse Event (TEAE) and Any Serious TEAE (Part 2)

End point title	Percentage of Participants With at Least One Treatment-emergent Adverse Event (TEAE) and Any Serious TEAE (Part 2)
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End point description:

Safety Analysis Part 2: All re-randomized participants at Week 24 who took at least a dose of study treatment on/or after Week 24. Any analysis based on the SAF2 was based on the treatment at Week 24, regardless of treatment according to the randomization.

End point type	Secondary
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End point timeframe:

Week 24 through Week 68

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	11	28
Units: percentage of participants				
number (not applicable)				
Percentage of Participants With at Least One TEAE	84.6	67.6	63.6	78.6
Percentage of Participants With Any Serious TEAE	7.7	2.9	0	7.1

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	32	7	34
Units: percentage of participants				
number (not applicable)				
Percentage of Participants With at Least One TEAE	66.7	87.5	57.1	67.6
Percentage of Participants With Any Serious TEAE	8.3	0	0	0

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
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Subject group type	Reporting group			
Number of subjects analysed	15			
Units: percentage of participants				
number (not applicable)				
Percentage of Participants With at Least One TEAE	66.7			
Percentage of Participants With Any Serious TEAE	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Treatment-emergent ADA (Part 1)

End point title	Percentage of Participants With Treatment-emergent ADA (Part 1) ^[2]
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End point description:

The Full Analysis Set (FAS1) for Part 1 included all randomized participants up to Week 24.

End point type	Secondary
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End point timeframe:

Baseline through Week 24

Notes:

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

Justification: ADA test is not applicable for Placebo arm.

End point values	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)	62.5 mg KY1005 (Part 1)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	77	76	77	77
Units: percentage of participants				
number (not applicable)				
% of Participants With Treatment-emergent ADA	2.6	6.4	13.2	32.1

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Treatment-emergent ADA (Part 2)

End point title	Percentage of Participants With Treatment-emergent ADA (Part 2)
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End point description:

The Full Analysis Set (FAS2) for Part 2 included all re-randomized at Week 24.

End point type	Secondary
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End point timeframe:

Baseline through Week 68

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	33	11	26
Units: percentage of participants				
number (not applicable)				
% of Participants With Treatment-emergent ADA	7.7	9.1	9.1	19.2

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	31	7	33
Units: percentage of participants				
number (not applicable)				
% of Participants With Treatment-emergent ADA	0	35.5	28.6	42.4

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in EASI (Eczema Area and Severity Index) (Part 2)

End point title	Absolute Change From Baseline in EASI (Eczema Area and Severity Index) (Part 2)
End point description: Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS2) for Part 2 included all re-randomized at Week 24. Only those participants with data available at specified timepoints are reported.	
End point type	Secondary
End point timeframe: Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52	

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 33 , 5, 33, 16)	-29.65 (± 11.278)	-26.28 (± 13.353)	-27.60 (± 11.170)	-18.90 (± 11.932)
Week 28 (N= 13, 34, 12, 28, 12, 31 , 7, 34, 14)	-30.51 (± 12.422)	-26.34 (± 14.353)	-25.86 (± 13.128)	-17.29 (± 12.458)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-29.08 (± 14.544)	-24.79 (± 15.775)	-22.99 (± 15.741)	-15.38 (± 12.620)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-28.15 (± 15.138)	-22.78 (± 17.505)	-22.27 (± 16.368)	-14.57 (± 13.550)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-28.54 (± 15.203)	-22.30 (± 17.908)	-22.56 (± 14.949)	-14.81 (± 13.178)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-28.43 (± 15.061)	-22.23 (± 17.487)	-23.07 (± 15.679)	-14.49 (± 12.877)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-22.15 (± 14.876)	-21.82 (± 17.764)	-22.24 (± 16.312)	-13.95 (± 13.596)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 31, 14)	-22.03 (± 14.889)	-19.59 (± 15.321)	-22.68 (± 15.418)	-13.89 (± 13.427)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 33 , 5, 33, 16)	-27.10 (± 12.670)	-22.45 (± 14.998)	-25.47 (± 12.209)	-22.41 (± 12.841)
Week 28 (N= 13, 34, 12, 28, 12, 31 , 7, 34, 14)	-26.37 (± 13.067)	-22.87 (± 15.667)	-23.79 (± 10.424)	-21.75 (± 13.106)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-27.36 (± 13.383)	-22.94 (± 14.915)	-24.94 (± 11.245)	-20.32 (± 14.189)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-27.51 (± 13.550)	-22.99 (± 14.978)	-24.65 (± 10.801)	-20.09 (± 15.098)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-27.96 (± 14.444)	-20.45 (± 16.659)	-25.51 (± 11.796)	-20.80 (± 14.343)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-27.49 (± 14.324)	-19.76 (± 16.561)	-22.34 (± 11.070)	-20.70 (± 14.343)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-27.72 (± 14.882)	-18.34 (± 16.959)	-23.88 (± 12.517)	-19.74 (± 15.277)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 31, 14)	-28.08 (± 16.097)	-17.30 (± 16.752)	-23.26 (± 11.789)	-20.81 (± 14.813)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 33 , 5, 33, 16)	-21.47 (± 10.420)			
Week 28 (N= 13, 34, 12, 28, 12, 31 , 7, 34, 14)	-21.69 (± 11.918)			
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-19.60 (± 10.632)			
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-20.20 (± 10.436)			
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-20.05 (± 10.596)			
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-20.43 (± 11.007)			
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-19.99 (± 11.292)			
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 31, 14)	-20.30 (± 11.526)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in EASI (Eczema Area and Severity Index) (Part 2)

End point title	Percentage Change From Baseline in EASI (Eczema Area and Severity Index) (Part 2)
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End point description:

Eczema Area and Severity Index-The EASI is an Investigator-assessed validated tool used to measure the extent (area) and severity of AD with scores from 0 to 72. Higher scores indicate worse condition. The Full Analysis Set (FAS2) for Part 2 included all re-randomized at Week 24. Only those participants with data available at specified timepoints are reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 28, 32, 36, 40, 44, 48 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: percentage of change				
arithmetic mean (standard deviation)				

Week 24 (N= 13, 34, 12, 28, 12, 33 , 5, 33, 16)	-91.71 (± 8.539)	-81.85 (± 31.624)	-84.20 (± 16.741)	-72.72 (± 41.299)
Week 28 (N= 13, 34, 12, 28, 12, 31 , 7, 34, 14)	-93.56 (± 8.382)	-81.47 (± 32.251)	-79.34 (± 28.091)	-66.53 (± 43.437)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-86.08 (± 24.896)	-76.51 (± 38.401)	-69.06 (± 38.468)	-58.78 (± 44.767)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-86.56 (± 28.656)	-69.33 (± 43.838)	-66.64 (± 39.631)	-56.24 (± 46.469)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-84.74 (± 28.948)	-65.65 (± 44.932)	-68.31 (± 38.024)	-57.39 (± 47.379)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-84.46 (± 28.757)	-66.73 (± 44.328)	-69.41 (± 38.731)	-56.30 (± 46.700)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-71.66 (± 40.416)	-65.18 (± 44.327)	-66.61 (± 39.645)	-53.59 (± 48.780)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 31, 14)	-71.22 (± 40.152)	-61.78 (± 44.406)	-68.09 (± 37.719)	-53.58 (± 48.725)

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 33 , 5, 33, 16)	-90.91 (± 10.585)	-62.46 (± 63.983)	-85.81 (± 10.212)	-76.74 (± 30.922)
Week 28 (N= 13, 34, 12, 28, 12, 31 , 7, 34, 14)	-87.78 (± 13.648)	-74.18 (± 42.104)	-89.88 (± 6.304)	-74.54 (± 31.665)
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-91.07 (± 13.744)	-75.64 (± 41.038)	-93.76 (± 4.960)	-68.09 (± 34.850)
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-91.22 (± 13.203)	-75.77 (± 40.984)	-93.0 (± 6.000)	-67.27 (± 40.162)
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-90.68 (± 13.737)	-64.68 (± 64.041)	-95.55 (± 5.011)	-70.11 (± 37.802)
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-90.18 (± 12.912)	-62.46 (± 63.983)	-83.57 (± 21.909)	-69.98 (± 37.145)
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-90.26 (± 12.961)	-57.47 (± 65.142)	-88.02 (± 22.234)	-66.63 (± 40.889)
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 31, 14)	-89.09 (± 15.625)	-54.42 (± 65.177)	86.51 (± 22.331)	-69.76 (± 38.241)

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percentage of change				
arithmetic mean (standard deviation)				
Week 24 (N= 13, 34, 12, 28, 12, 33 , 5, 33, 16)	-78.51 (± 28.977)			

Week 28 (N= 13, 34, 12, 28, 12, 31 , 7, 34, 14)	-76.87 (± 31.377)			
Week 32 (N= 13, 34, 11, 28 12, 32, 7, 32, 15)	-71.98 (± 33.063)			
Week 36 (N= 13, 33, 10, 28, 12, 32, 7, 32, 15)	-74.93 (± 32.664)			
Week 40 (N= 13, 31, 11, 28, 11, 32, 7, 31, 15)	-74.05 (± 32.343)			
Week 44 (N= 13, 32, 11, 28, 12, 32, 7, 31, 14)	-72.99 (± 33.353)			
Week 48 (N= 13, 32, 10, 28, 12, 30, 7, 30, 14)	-70.92 (± 33.888)			
Week 52 (N= 13, 31, 11, 28, 11, 29, 7, 31, 14)	-72.04 (± 34.827)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Improvement (Reduction) of Weekly Average of Pruritus NRS (Numerical Rating Scale) ≥ 4 With a Baseline Pruritus of ≥ 4 From Baseline (Part 2)

End point title	Percentage of Participants With Improvement (Reduction) of Weekly Average of Pruritus NRS (Numerical Rating Scale) ≥ 4 With a Baseline Pruritus of ≥ 4 From Baseline (Part 2)
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End point description:

The pruritus NRS is a simple assessment tool to report the intensity of their pruritus (itch) ranges from 0 to 10 with 0 being 'no itch' and 10 being the 'worst itch imaginable'.

The Full Analysis Set (FAS2) for Part 2 included all re-randomized at Week 24. Only those participants with data available at specified time points are reported.

End point type	Secondary
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End point timeframe:

Baseline to Weeks 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51 and 52

End point values	250 mg KY1005 Re-Randomized From the 250 mg (LD) Arm (Part 2)	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	34	12	28
Units: percentage of participants				
number (not applicable)				
Week 24	53.8	41.2	75.0	35.7
Week 25	53.8	41.2	66.7	39.3
Week 26	53.8	39.2	66.7	32.1
Week 27	61.5	35.3	58.3	28.6
Week 28	61.5	35.3	66.7	35.7
Week 29	69.2	38.2	50.0	25.0
Week 30	61.5	44.1	58.3	25.0

Week 31	61.5	41.2	58.3	25.0
Week 32	61.5	47.1	50.0	25.0
Week 33	61.5	47.1	58.3	28.6
Week 34	61.5	41.2	75.0	21.4
Week 35	61.5	41.2	66.7	21.4
Week 36	61.5	38.2	58.3	21.4
Week 37	53.8	41.2	50.0	28.6
Week 38	53.8	35.3	50.0	25.0
Week 39	53.8	41.2	50.0	25.0
Week 40	53.8	38.2	33.3	25.0
Week 41	61.5	35.3	41.7	28.6
Week 42	53.8	38.2	50.0	28.6
Week 43	53.8	35.3	50.0	28.6
Week 44	61.5	38.2	41.7	21.4
Week 45	61.5	41.2	41.7	21.4
Week 46	53.8	44.1	50.0	28.6
Week 47	46.2	38.2	33.3	28.6
Week 48	38.5	35.3	41.7	28.6
Week 49	38.5	41.2	50.0	35.7
Week 50	38.5	35.3	50.0	32.1
Week 51	30.8	32.4	41.7	28.6
Week 52	46.2	29.4	41.7	25.0

End point values	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	33	7	35
Units: percentage of participants				
number (not applicable)				
Week 24	58.3	45.5	71.4	45.7
Week 25	66.7	39.4	57.1	37.1
Week 26	58.3	33.3	71.4	42.9
Week 27	58.3	39.4	71.4	37.1
Week 28	58.3	42.4	57.1	37.1
Week 29	58.3	45.5	57.1	40.0
Week 30	66.7	36.4	42.9	42.9
Week 31	66.7	36.4	42.9	40.0
Week 32	75.0	42.4	71.4	40.0
Week 33	58.3	42.4	71.4	40.0
Week 34	75.0	30.3	42.9	37.1
Week 35	66.7	39.4	71.4	34.3
Week 36	66.7	42.4	71.4	40.0
Week 37	66.7	42.4	71.4	37.1
Week 38	58.3	42.4	71.4	31.4
Week 39	58.3	39.4	71.4	31.4
Week 40	58.3	36.4	28.6	31.4

Week 41	66.7	39.4	57.1	34.3
Week 42	66.7	36.4	42.9	31.4
Week 43	58.3	36.4	42.9	34.3
Week 44	75.0	39.4	42.9	37.1
Week 45	75.0	36.4	42.9	40.0
Week 46	50.0	27.3	42.9	37.1
Week 47	58.3	30.3	42.9	45.7
Week 48	66.7	27.3	57.1	37.1
Week 49	66.7	30.3	57.1	40.0
Week 50	66.7	24.2	57.1	37.1
Week 51	58.3	27.3	42.9	34.3
Week 52	66.7	27.3	57.1	40.0

End point values	Placebo (Part 2) Continued From Part 1 Placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: percentage of participants				
number (not applicable)				
Week 24	25.0			
Week 25	31.3			
Week 26	25.0			
Week 27	25.0			
Week 28	25.0			
Week 29	25.0			
Week 30	18.8			
Week 31	18.8			
Week 32	18.8			
Week 33	18.8			
Week 34	25.0			
Week 35	25.0			
Week 36	25.0			
Week 37	18.8			
Week 38	18.8			
Week 39	25.0			
Week 40	25.0			
Week 41	31.3			
Week 42	25.0			
Week 43	31.3			
Week 44	25.0			
Week 45	31.3			
Week 46	31.3			
Week 47	25.0			
Week 48	25.0			
Week 49	25.0			
Week 50	25.0			
Week 51	25.0			
Week 52	25.0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The Adverse events were reported in the timeframe for Part 1 from Baseline to Week 24 + 16 weeks follow up period and for patients enrolled in Part 2 from Week 24 to Week 52 plus 16 weeks follow-up period.

Adverse event reporting additional description:

The total number of patients in AEs reporting is different for Part 1 and Part 2.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	250 mg (500 mg LD) KY1005 (Part 1)
Reporting group description: -	
Reporting group title	250 mg (no LD) KY1005 (Part 1)
Reporting group description: -	
Reporting group title	125 mg KY1005 (Part 1)
Reporting group description: -	
Reporting group title	62.5 mg KY1005 (Part 1)
Reporting group description: -	
Reporting group title	Placebo (Part 1)
Reporting group description: -	
Reporting group title	250 mg KY1005 Re-Randomized From the (LD) Arm (Part 2)
Reporting group description: -	
Reporting group title	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)
Reporting group description: -	
Reporting group title	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)
Reporting group description: -	
Reporting group title	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Reporting group description: -	
Reporting group title	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)
Reporting group description: -	
Reporting group title	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)
Reporting group description: -	
Reporting group title	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)
Reporting group description: -	
Reporting group title	Placebo Re-randomized From the 62.5 mg Arm (Part 2)
Reporting group description: -	
Reporting group title	Placebo Continued From Part 1 Placebo (Part 2)
Reporting group description: -	

Serious adverse events	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 77 (2.60%)	0 / 78 (0.00%)	1 / 77 (1.30%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Forearm fracture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 77 (1.30%)	0 / 78 (0.00%)	0 / 77 (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
Nervous system disorders			
Tension headache			
subjects affected / exposed	1 / 77 (1.30%)	0 / 78 (0.00%)	0 / 77 (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
Gastrointestinal disorders			
Haemorrhoidal haemorrhage			

subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis bullous			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 77 (1.30%)	0 / 78 (0.00%)	0 / 77 (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			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Metabolic acidosis			
subjects affected / exposed	1 / 77 (1.30%)	0 / 78 (0.00%)	0 / 77 (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
Abnormal loss of weight			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	62.5 mg KY1005 (Part 1)	Placebo (Part 1)	250 mg KY1005 Re-Randomized From the (LD) Arm (Part 2)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 78 (6.41%)	1 / 78 (1.28%)	1 / 13 (7.69%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Forearm fracture			
subjects affected / exposed	1 / 78 (1.28%)	0 / 78 (0.00%)	0 / 13 (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
Ankle fracture			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			

subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 78 (0.00%)	1 / 78 (1.28%)	0 / 13 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Tension headache			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 78 (1.28%)	0 / 78 (0.00%)	0 / 13 (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
Umbilical hernia			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis bullous			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			

subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 78 (0.00%)	0 / 13 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 78 (0.00%)	0 / 13 (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
Pharyngitis			
subjects affected / exposed	1 / 78 (1.28%)	0 / 78 (0.00%)	0 / 13 (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
Metabolism and nutrition disorders			
Metabolic acidosis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal loss of weight			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 34 (2.94%)	0 / 11 (0.00%)	2 / 28 (7.14%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Forearm fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	1 / 34 (2.94%)	0 / 11 (0.00%)	0 / 28 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Tension headache			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis bullous			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Metabolic acidosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal loss of weight			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	1 / 28 (3.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Forearm fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (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
Tendon rupture			

subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis bullous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			

subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Metabolic acidosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal loss of weight			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo Re-randomized From the 62.5 mg Arm (Part 2)	Placebo Continued From Part 1 Placebo (Part 2)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Forearm fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Tension headache			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis bullous			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Metabolic acidosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abnormal loss of weight			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences causally related to treatment / all	0 / 0	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	250 mg (500 mg LD) KY1005 (Part 1)	250 mg (no LD) KY1005 (Part 1)	125 mg KY1005 (Part 1)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	42 / 77 (54.55%)	39 / 78 (50.00%)	39 / 77 (50.65%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 77 (2.60%)	1 / 78 (1.28%)	1 / 77 (1.30%)
occurrences (all)	2	1	1
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	1 / 77 (1.30%)	1 / 78 (1.28%)	0 / 77 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Immune system disorders			

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Rhinitis allergic subjects affected / exposed occurrences (all)	1 / 77 (1.30%) 1	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	2 / 77 (2.60%) 2	0 / 78 (0.00%) 0	2 / 77 (2.60%) 2
Investigations Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	4 / 77 (5.19%) 5	2 / 78 (2.56%) 2	0 / 77 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	2 / 77 (2.60%) 3	2 / 78 (2.56%) 2	1 / 77 (1.30%) 1
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	1 / 78 (1.28%) 1	0 / 77 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	1 / 77 (1.30%) 1	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Injury, poisoning and procedural complications			

Accidental overdose subjects affected / exposed occurrences (all)	1 / 77 (1.30%) 1	3 / 78 (3.85%) 3	1 / 77 (1.30%) 1
Muscle strain subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	4 / 77 (5.19%) 4	4 / 78 (5.13%) 4	4 / 77 (5.19%) 4
Dizziness subjects affected / exposed occurrences (all)	2 / 77 (2.60%) 2	0 / 78 (0.00%) 0	2 / 77 (2.60%) 3
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Tension headache subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 77 (1.30%) 1	2 / 78 (2.56%) 2	1 / 77 (1.30%) 1
Food poisoning subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	1 / 77 (1.30%) 1	0 / 78 (0.00%) 0	1 / 77 (1.30%) 1
Skin and subcutaneous tissue disorders			
Dermatitis atopic subjects affected / exposed occurrences (all)	9 / 77 (11.69%) 10	16 / 78 (20.51%) 22	15 / 77 (19.48%) 19
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Rash			

subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Rosacea subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	1 / 77 (1.30%) 1	0 / 78 (0.00%) 0	1 / 77 (1.30%) 1
Spinal pain subjects affected / exposed occurrences (all)	2 / 77 (2.60%) 2	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	1 / 77 (1.30%) 1	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Periostitis subjects affected / exposed occurrences (all)	0 / 77 (0.00%) 0	0 / 78 (0.00%) 0	0 / 77 (0.00%) 0
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	14 / 77 (18.18%) 19	6 / 78 (7.69%) 8	9 / 77 (11.69%) 12
COVID-19 subjects affected / exposed occurrences (all)	6 / 77 (7.79%) 6	7 / 78 (8.97%) 7	7 / 77 (9.09%) 7
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 77 (2.60%) 2	2 / 78 (2.56%) 3	4 / 77 (5.19%) 4
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 77 (2.60%) 2	3 / 78 (3.85%) 3	2 / 77 (2.60%) 3
Oral herpes subjects affected / exposed occurrences (all)	2 / 77 (2.60%) 2	1 / 78 (1.28%) 1	1 / 77 (1.30%) 1
Folliculitis			

subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	3
Rhinitis			
subjects affected / exposed	2 / 77 (2.60%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences (all)	2	0	0
Pharyngitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Dermatitis infected			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	2 / 77 (2.60%)	1 / 78 (1.28%)	1 / 77 (1.30%)
occurrences (all)	2	1	1
Sinusitis			
subjects affected / exposed	1 / 77 (1.30%)	1 / 78 (1.28%)	1 / 77 (1.30%)
occurrences (all)	2	1	1
Tonsillitis			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 77 (0.00%)	1 / 78 (1.28%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Postoperative wound infection			
subjects affected / exposed	2 / 77 (2.60%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences (all)	2	0	0
Herpes simplex			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 77 (0.00%)	1 / 78 (1.28%)	0 / 77 (0.00%)
occurrences (all)	0	3	0
Bronchitis viral			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Otitis media			

subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 77 (0.00%)	0 / 78 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	62.5 mg KY1005 (Part 1)	Placebo (Part 1)	250 mg KY1005 Re- Randomized From the (LD) Arm (Part 2)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 78 (52.56%)	41 / 78 (52.56%)	11 / 13 (84.62%)
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 78 (5.13%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	4	0	0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 78 (1.28%)	1 / 78 (1.28%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Heavy menstrual bleeding			

subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 78 (1.28%) 1	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Investigations			
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	2 / 78 (2.56%) 2	2 / 78 (2.56%) 2	0 / 13 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 78 (1.28%) 1	1 / 78 (1.28%) 1	0 / 13 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 78 (1.28%) 1	1 / 78 (1.28%) 1	0 / 13 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Injury, poisoning and procedural complications			
Accidental overdose subjects affected / exposed occurrences (all)	2 / 78 (2.56%) 2	1 / 78 (1.28%) 1	0 / 13 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	7 / 78 (8.97%) 7	2 / 78 (2.56%) 2	2 / 13 (15.38%) 2
Dizziness subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	1 / 78 (1.28%) 1	0 / 13 (0.00%) 0
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Tension headache subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all)	2 / 78 (2.56%) 2	1 / 78 (1.28%) 1	0 / 13 (0.00%) 0
Food poisoning subjects affected / exposed occurrences (all)	1 / 78 (1.28%) 1	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	1 / 13 (7.69%) 1
Skin and subcutaneous tissue disorders Dermatitis atopic subjects affected / exposed occurrences (all)	13 / 78 (16.67%) 14	30 / 78 (38.46%) 43	6 / 13 (46.15%) 8
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	1 / 13 (7.69%) 1
Rash subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	1 / 13 (7.69%) 1
Rosacea subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	1 / 78 (1.28%)	2 / 78 (2.56%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Spinal pain			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 78 (1.28%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Periostitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	5 / 78 (6.41%)	7 / 78 (8.97%)	2 / 13 (15.38%)
occurrences (all)	5	10	2
COVID-19			
subjects affected / exposed	4 / 78 (5.13%)	5 / 78 (6.41%)	0 / 13 (0.00%)
occurrences (all)	4	5	0
Upper respiratory tract infection			
subjects affected / exposed	5 / 78 (6.41%)	5 / 78 (6.41%)	0 / 13 (0.00%)
occurrences (all)	6	5	0
Viral upper respiratory tract infection			
subjects affected / exposed	4 / 78 (5.13%)	2 / 78 (2.56%)	0 / 13 (0.00%)
occurrences (all)	7	3	0
Oral herpes			
subjects affected / exposed	1 / 78 (1.28%)	1 / 78 (1.28%)	0 / 13 (0.00%)
occurrences (all)	2	1	0
Folliculitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 78 (0.00%)	1 / 78 (1.28%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			

subjects affected / exposed	1 / 78 (1.28%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Dermatitis infected			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 78 (1.28%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 78 (1.28%)	1 / 78 (1.28%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Cystitis			
subjects affected / exposed	0 / 78 (0.00%)	1 / 78 (1.28%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Postoperative wound infection			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bronchitis viral			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 78 (0.00%)	0 / 78 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pyuria			

subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	1 / 13 (7.69%) 1
Metabolism and nutrition disorders Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 78 (0.00%) 0	0 / 78 (0.00%) 0	0 / 13 (0.00%) 0

Non-serious adverse events	Placebo Re-Randomized From the 250 mg (LD) Arm (Part 2)	250mg KY1005 Re-randomized From the 250 mg (no LD) Arm(Part 2)	Placebo Re-Randomized From the 250 mg (no LD) Arm (Part 2)
Total subjects affected by non-serious adverse events subjects affected / exposed	21 / 34 (61.76%)	7 / 11 (63.64%)	19 / 28 (67.86%)
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
General disorders and administration site conditions Influenza like illness subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 11 (9.09%) 1	0 / 28 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Rhinitis allergic			

subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	1 / 28 (3.57%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Investigations			
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Injury, poisoning and procedural complications			
Accidental overdose subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 11 (0.00%) 0	0 / 28 (0.00%) 0
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 11 (9.09%) 1	1 / 28 (3.57%) 1
Dizziness			

subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	0	2
Food poisoning			
subjects affected / exposed	0 / 34 (0.00%)	1 / 11 (9.09%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	14 / 34 (41.18%)	3 / 11 (27.27%)	15 / 28 (53.57%)
occurrences (all)	21	4	19
Dermatitis acneiform			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 34 (0.00%)	1 / 11 (9.09%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Spinal pain			

subjects affected / exposed	1 / 34 (2.94%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Periostitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 34 (11.76%)	1 / 11 (9.09%)	2 / 28 (7.14%)
occurrences (all)	4	1	2
COVID-19			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 34 (5.88%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	3	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	4 / 11 (36.36%)	0 / 28 (0.00%)
occurrences (all)	0	4	0
Oral herpes			
subjects affected / exposed	1 / 34 (2.94%)	0 / 11 (0.00%)	1 / 28 (3.57%)
occurrences (all)	1	0	1
Folliculitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 11 (0.00%)	2 / 28 (7.14%)
occurrences (all)	1	0	2
Dermatitis infected			
subjects affected / exposed	4 / 34 (11.76%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	4	0	0

Influenza			
subjects affected / exposed	1 / 34 (2.94%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 11 (9.09%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 11 (9.09%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	1 / 34 (2.94%)	1 / 11 (9.09%)	0 / 28 (0.00%)
occurrences (all)	1	1	0
Urinary tract infection			
subjects affected / exposed	1 / 34 (2.94%)	1 / 11 (9.09%)	0 / 28 (0.00%)
occurrences (all)	1	1	0
Bronchitis viral			
subjects affected / exposed	0 / 34 (0.00%)	1 / 11 (9.09%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			

subjects affected / exposed	0 / 34 (0.00%)	0 / 11 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	125 mg KY1005 Re-randomized From the 125 mg Arm (Part 2)	Placebo Re-randomized From the 125 mg KY1005 Arm (Part 2)	62.5 mg Re-Randomized From the 62.5 mg KY1005 Arm (Part 2)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 12 (66.67%)	27 / 32 (84.38%)	4 / 7 (57.14%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	1 / 32 (3.13%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 32 (3.13%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Alanine aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 12 (0.00%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Muscle strain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 12 (16.67%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Dizziness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tension headache			

subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Food poisoning subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	14 / 32 (43.75%) 17	1 / 7 (14.29%) 1
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Rosacea subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	2 / 32 (6.25%) 2	1 / 7 (14.29%) 2
Spinal pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Periostitis			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 32 (0.00%) 0	0 / 7 (0.00%) 0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	5 / 32 (15.63%)	0 / 7 (0.00%)
occurrences (all)	0	6	0
COVID-19			
subjects affected / exposed	1 / 12 (8.33%)	1 / 32 (3.13%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 32 (3.13%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)	1 / 32 (3.13%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Oral herpes			
subjects affected / exposed	1 / 12 (8.33%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Folliculitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 32 (3.13%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	1 / 12 (8.33%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Dermatitis infected			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 12 (0.00%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Sinusitis			
subjects affected / exposed	1 / 12 (8.33%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	1	2	0

Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 32 (3.13%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Postoperative wound infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Bronchitis viral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 32 (3.13%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pyuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 32 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 32 (6.25%)	0 / 7 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Placebo Re-randomized From the 62.5 mg Arm (Part 2)	Placebo Continued From Part 1 Placebo (Part 2)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 34 (61.76%)	10 / 15 (66.67%)	

Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	
General disorders and administration site conditions Influenza like illness subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0 3 / 34 (8.82%) 3	0 / 15 (0.00%) 0 0 / 15 (0.00%) 0	
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all) Heavy menstrual bleeding subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2 0 / 34 (0.00%) 0	0 / 15 (0.00%) 0 0 / 15 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Rhinitis allergic subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0 0 / 34 (0.00%) 0	1 / 15 (6.67%) 1 0 / 15 (0.00%) 0	
Investigations Blood creatine phosphokinase increased subjects affected / exposed occurrences (all) Alanine aminotransferase increased subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2 0 / 34 (0.00%) 0	0 / 15 (0.00%) 0 0 / 15 (0.00%) 0	

Aspartate aminotransferase increased			
subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)	
occurrences (all)	1	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	
occurrences (all)	1	1	
Muscle strain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)	
occurrences (all)	1	1	
Dizziness			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Hypoaesthesia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Tension headache			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Food poisoning			

subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 15 (0.00%) 0	
Abdominal pain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	
Skin and subcutaneous tissue disorders Dermatitis atopic subjects affected / exposed occurrences (all)	12 / 34 (35.29%) 13	4 / 15 (26.67%) 5	
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	
Rash subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	
Rosacea subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 15 (0.00%) 0	
Spinal pain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	2 / 15 (13.33%) 2	
Muscle spasms subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 15 (6.67%) 1	
Periostitis subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 15 (6.67%) 1	
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	3 / 34 (8.82%) 4	2 / 15 (13.33%) 3	
COVID-19			

subjects affected / exposed	1 / 34 (2.94%)	0 / 15 (0.00%)
occurrences (all)	1	0
Upper respiratory tract infection		
subjects affected / exposed	3 / 34 (8.82%)	1 / 15 (6.67%)
occurrences (all)	3	1
Viral upper respiratory tract infection		
subjects affected / exposed	0 / 34 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	2
Oral herpes		
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0
Folliculitis		
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)
occurrences (all)	1	1
Rhinitis		
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0
Pharyngitis		
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0
Dermatitis infected		
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0
Influenza		
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0
Sinusitis		
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0
Tonsillitis		
subjects affected / exposed	1 / 34 (2.94%)	1 / 15 (6.67%)
occurrences (all)	1	1
Cystitis		
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0
Postoperative wound infection		

subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Bronchitis viral			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Otitis media			
subjects affected / exposed	0 / 34 (0.00%)	1 / 15 (6.67%)	
occurrences (all)	0	1	
Fungal skin infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Pyuria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 15 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 September 2021	<p>Amended Protocol 2</p> <p>Key changes included various clarifications to the text and updates to:</p> <ul style="list-style-type: none"> • management of patients who continued to respond to IMP at Day 365 (Week 52), and enter safety follow-up instead of LTE; • add definition of loss of clinical response; • impact of KY1005 on vaccination response in AD has not been tested to date; • primary analysis timepoint at Day 169 (W24) visit; • randomization stratification by IGA response at W24; • frequency of IDMC meetings and data reviewed; • definition of women of non-child bearing potential; • participant contraceptive requirements; • abnormal pregnancy outcomes; • report of symptomatic overdose as an AESI within 24 hours of learning of the event; • collection of prior systemic therapies for any indication with reason for discontinuation; • frequency of physical examinations; • definition of body surface area; • definition of mild, moderate, and severe AEs and TEAEs; • liver function severe laboratory abnormalities requiring permanent discontinuation of IMP; • intended use of data collected regarding the impact of COVID-19 or other pandemics; • add AE and rescue therapy stopping criteria; and • specify sample processing to the Bioanalytical laboratory.
14 December 2021	<p>Amended Protocol 4</p> <ul style="list-style-type: none"> • To fulfil requirement from PMDA, Japan, a clarification was added regarding Hepatitis serology testing. • Hypersensitivity to KY1005 including excipients added as an exclusion criterion was added. • Any prior receipt of any anti-OX40 or anti-OX40L, including KY1005 as an exclusion criterion was added.
18 January 2022	<p>Amended Protocol 5</p> <ul style="list-style-type: none"> • To fulfil requirement from the MHRA, UK, country-specific clarification was added to an inclusion criterion. • Clarification was added that LTE is a separate study to KY1005-CT05 (DRI17366). • Specific exclusionary levels of hepatic (aspartate aminotransferase, alanine aminotransferase, and total bilirubin, including total bilirubin levels for subjects with Gilbert's syndrome) and renal function test were added. • Hypersensitivity to the components of the placebo formulation as an exclusion criterion was added. • Rationale for inclusion of 62.5 mg dose level was clarified in this dose ranging study, and additional safety considerations were outlined for all 4 dose levels. • Clarification was added that the biopsy was done only at selected sites on those patients who agree to enroll into the skin biopsy sub-study, and the biopsy was not conducted in patients if there was a contraindication to the procedure in the Investigator's opinion. • Other clarifications were made concerning the biopsy, dose level discontinuation, definition of women of childbearing potential, Common Terminology Criteria for Adverse Events grading scale, responsibilities in the event of blind break, monitoring of AEs by Investigators, and re-challenge. • Addition of final safety follow-up visit at Day 477 (Week 68) as requested to take into consideration 5 elimination half-lives of IMP. Anti-drug antibody collection from Day 449 (Week 64) was postponed to Day 477 (Week 68) to match the last visit.

01 March 2022	<p>Amended Protocol 8</p> <ul style="list-style-type: none"> • To fulfil requirements from the German authorities PEI and EC of the State of Berlin (Ethik-Kommission des Landes Berlin) with global impact, requirements from Czech Health Authorities (STÁTNÍ ÚSTAV PRO KONTROLU LÉČIV), and requirements from Hungarian Emberi Erőforrások Minisztériuma, (Ministry of Human Capacities). • Interim analysis was added to obtain early information for planning the Phase 3 program and to support the timely analysis of data from participants who completed the Day 113 (Week 16) assessments. No study conduct was modified based on interim analysis results. • Also, the inclusion of an interim analysis, modification in the biopsy requirements, and overall clarifications.
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported