Clinical trial results:
A Phase 2a, Randomized, Double-blinded, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI9929 in Adult Subjects with Moderate-to-Severe Atopic Dermatitis

Summary

EudraCT number	2015-000595-10
Trial protocol	DE HU
Global end of trial date	15 July 2016

Results information

Result version number	v1 (current)
This version publication date	01 November 2017
First version publication date	01 November 2017

Trial information

Trial identification

Sponsor protocol code	D5240C00001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02525094
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedImmune Ltd
Sponsor organisation address	Milstein Building, Granta Park, Cambridge, United Kingdom, CB21 6GH
Public contact	AstraZeneca, AstraZeneca Clinical Study Information Center, +1 1-877-240-9479, information.center@astrazeneca.com
Scientific contact	AstraZeneca, AstraZeneca Clinical Study Information Center, +1 1-877-240-9479, information.center@astrazeneca.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 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 July 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of trial was to evaluate the effect of MEDI9929 compared with placebo in adult participants with moderate to-severe Atopic Dermatitis (AD), assessed using the change from baseline in Eczema Area and Severity Index (EASI) at Week 12.

Protection of trial subjects:

The conduct of this clinical study met all local and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with International Conference on Harmonization guideline: Good Clinical Practice and applicable regulatory requirements. Subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy:

All participants received maintenance therapy of Class 3 topical corticosteroids (TCS) cream or ointment for lesional skin from the start of the run-in period (Visit 2, Week -2) to Week 22.

Evidence for comparator: -

Actual start date of recruitment	29 August 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 13
Country: Number of subjects enrolled	Canada: 12
Country: Number of subjects enrolled	Germany: 36
Country: Number of subjects enrolled	Hungary: 15
Country: Number of subjects enrolled	New Zealand: 1
Country: Number of subjects enrolled	United States: 34
Worldwide total number of subjects	111
EEA total number of subjects	51

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	105
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted from 29Aug2015 to 15Jul2016.

Pre-assignment

Screening details:

A total of 155 participants were screened, of which 113 were randomized. Out of 113 participants, 111 were treated in the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received 6 subcutaneous doses of placebo every 2 weeks for 12 weeks, with the last dose at Week 10.

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 administered as 6 subcutaneous doses for every 2 weeks for 12 weeks, with the last dose at Week 10.

Arm title	MEDI9929 280 mg

Arm description:

Participants received 6 subcutaneous doses of MEDI9929 280 mg every 2 weeks for 12 weeks, with the last dose at Week 10.

Arm type	Experimental
Investigational medicinal product name	MEDI9929
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

MEDI9929 was administered at the dose of 280 mg every 2 weeks for 12 weeks, with the last dose at Week 10.

Number of subjects in period 1	Placebo	MEDI9929 280 mg
Started	56	55
Completed	49	48
Not completed	7	7
Consent withdrawn by subject	5	6
Lost to follow-up	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received 6 subcutaneous doses of placebo every 2 weeks for 12 weeks, with the last dose at Week 10.	
Reporting group title	MEDI9929 280 mg
Reporting group description:	
Participants received 6 subcutaneous doses of MEDI9929 280 mg every 2 weeks for 12 weeks, with the last dose at Week 10.	

Reporting group values	Placebo	MEDI9929 280 mg	Total
Number of subjects	56	55	111
Age Categorical Units: Subjects			
18-35 years	28	27	55
36-75 years	28	28	56
Age Continuous Units: Years			
arithmetic mean	38.8	38.5	
standard deviation	± 15.3	± 14.9	-
Gender, Male/Female Units: Subjects			
Female	26	23	49
Male	30	32	62
Eczema Area and Severity Index Score			
The eczema area and severity index (EASI) evaluates 4 natural anatomical regions for severity (0 [none] to 3 [severe]) and extent of key disease signs and focuses on the key acute and chronic signs of inflammation (erythema, induration/papulation, excoriation, and lichenification). The total score is the sum of the four body-region scores, maximum=72, minimum=0. The higher values indicating more severe disease.			
Units: Subjects			
<= 25 points	36	33	69
> 25 points	20	22	42
Investigator's Global Assessment			
The investigator’s global assessment (IGA) allows investigators to assess overall disease severity at one given time point and consists of a 5-point severity scale from clear to severe disease (0 = clear, 1 = almost clear, 2 = mild disease, 3 = moderate disease, and 4 = severe disease).			
Units: Subjects			
Category 2	0	1	1
Category 3	46	44	90
Category 4	10	10	20
Atopic Dermatitis Status Units: Subjects			
IgE >= 150 kU/L and Positive Serum Specific IgEa	50	47	97
IgE >= 150 kU/L and Negative Serum Specific IgE	2	0	2
IgE < 150 kU/L and Positive Serum Specific IgE	3	3	6

IgE < 150 kU/L and Negative Serum Specific IgEb	1	3	4
Missing	0	2	2

Subject analysis sets

Subject analysis set title	MEDI9929 280mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received 6 subcutaneous doses of MEDI9929 280 mg every 2 weeks for 12 weeks, with the last dose at Week 10. Participants who received at least one dose of MEDI9929 during the study, regardless of randomized treatment assignment, were analyzed under MEDI9929 group. One participant who randomized to placebo group but received an incorrect first dose of MEDI9929 was included in the "MEDI9929" group. An arbitrary value of '99999' indicates value was not estimable.

Reporting group values	MEDI9929 280mg		
Number of subjects	56		
Age Categorical Units: Subjects			
18-35 years			
36-75 years			
Age Continuous Units: Years			
arithmetic mean	38.5		
standard deviation	± 14.9		
Gender, Male/Female Units: Subjects			
Female			
Male			
Eczema Area and Severity Index Score			
The eczema area and severity index (EASI) evaluates 4 natural anatomical regions for severity (0 [none] to 3 [severe]) and extent of key disease signs and focuses on the key acute and chronic signs of inflammation (erythema, induration/papulation, excoriation, and lichenification). The total score is the sum of the four body-region scores, maximum=72, minimum=0. The higher values indicating more severe disease.			
Units: Subjects			
<= 25 points	99999		
> 25 points			
Investigator's Global Assessment			
The investigator’s global assessment (IGA) allows investigators to assess overall disease severity at one given time point and consists of a 5-point severity scale from clear to severe disease (0 = clear, 1 = almost clear, 2 = mild disease, 3 = moderate disease, and 4 = severe disease).			
Units: Subjects			
Category 2			
Category 3			
Category 4			
Atopic Dermatitis Status Units: Subjects			
IgE >= 150 kU/L and Positive Serum Specific IgEa			
IgE >= 150 kU/L and Negative Serum Specific IgE			
IgE < 150 kU/L and Positive Serum Specific IgE			

IgE < 150 kU/L and Negative Serum Specific IgEb Missing			

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received 6 subcutaneous doses of placebo every 2 weeks for 12 weeks, with the last dose at Week 10.	
Reporting group title	MEDI9929 280 mg
Reporting group description:	
Participants received 6 subcutaneous doses of MEDI9929 280 mg every 2 weeks for 12 weeks, with the last dose at Week 10.	
Subject analysis set title	MEDI9929 280mg
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received 6 subcutaneous doses of MEDI9929 280 mg every 2 weeks for 12 weeks, with the last dose at Week 10. Participants who received at least one dose of MEDI9929 during the study, regardless of randomized treatment assignment, were analyzed under MEDI9929 group. One participant who randomized to placebo group but received an incorrect first dose of MEDI9929 was included in the "MEDI9929" group. An arbitrary value of '99999' indicates value was not estimable.	

Primary: Percentage of Participants Achieving Greater Than or Equal to (>=) 50 Percent (%) Reduction From Baseline in Eczema Area and Severity Index (EASI 50) at Week 12

End point title	Percentage of Participants Achieving Greater Than or Equal to (>=) 50 Percent (%) Reduction From Baseline in Eczema Area and Severity Index (EASI 50) at Week 12
End point description:	
The eczema area and severity index (EASI) evaluates 4 natural anatomical regions for severity (0 [none] to 3 [severe]) and extent of key disease signs and focuses on the key acute and chronic signs of inflammation (erythema, induration/papulation, excoriation, and lichenification). The total score is the sum of the four body-region scores, maximum=72, minimum=0. The higher values indicating more severe disease. The EASI50 responder defined as a participant who achieved at least 50% reduction in EASI score from baseline. Intent-To-Treat (ITT) population included all participants who were randomized and received any study investigational product.	
End point type	Primary
End point timeframe:	
Week 12	

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	55		
Units: Percentage of particpants				
number (not applicable)	48.2	64.7		

Statistical analyses

Statistical analysis title	Placebo vs MEDI9929 280mg
Comparison groups	MEDI9929 280 mg v Placebo

Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Odds ratio (OR)
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	4.33

Secondary: Percentage of Participants Achieving >= 75 % Reduction From Baseline in EASI75 at Week 12

End point title	Percentage of Participants Achieving >= 75 % Reduction From Baseline in EASI75 at Week 12

End point description:

The EASI evaluates 4 natural anatomical regions for severity (0 [none] to 3 [severe]) and extent of key disease signs and focuses on the key acute and chronic signs of inflammation (erythema, induration/papulation, excoriation, and lichenification). The total score is the sum of the four body-region scores, maximum=72, minimum=0. The higher values indicating more severe disease. The EASI75 responder defined as a participant who achieves at least a 75% reduction in EASI score from baseline. ITT population included all participants who were randomized and received any study investigational product.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	55		
Units: Percentage of particpants				
number (not applicable)	19.8	24.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in EASI Total Score at Week 12

End point title	Mean Change From Baseline in EASI Total Score at Week 12

End point description:

The EASI evaluates 4 natural anatomical regions for severity (0 [none] to 3 [severe]) and extent of key disease signs and focuses on the key acute and chronic signs of inflammation (erythema, induration/papulation, excoriation, and lichenification). The total score is the sum of the four body-region scores, maximum=72, minimum=0. The higher values indicating more severe disease. ITT population included all participants who were randomized and received any study investigational product. Here, "n" is number of participants analysed for this time point.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 12

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	55		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=56, 55)	24.48 (± 11.21)	24.05 (± 12.38)		
Week 12 (n=50, 49)	-11.23 (± 8.73)	-12.16 (± 9.96)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Investigator's Global Assessment (IGA) Response of 0 (Clear) or 1 (Almost Clear) and at Least a 2-Grade Reduction From Baseline

End point title	Percentage of Participants Achieving Investigator's Global Assessment (IGA) Response of 0 (Clear) or 1 (Almost Clear) and at Least a 2-Grade Reduction From Baseline

End point description:

The investigator’s global assessment (IGA) allows investigators to assess overall disease severity at one given time point and consists of a 5-point severity scale from clear to severe disease (0 = clear, 1 = almost clear, 2 = mild disease, 3 = moderate disease, and 4 = severe disease). A participant has IGA response if they achieve a score of 0 (clear) or 1 (almost clear) and at least a 2-grade reduction from baseline. ITT population included all participants who were randomized and received any study investigational product.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	55		
Units: Percentage of particpants				
number (not applicable)	12.8	19.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in the Scoring of Atopic Dermatitis (SCORAD) at Week 12

End point title	Mean Change From Baseline in the Scoring of Atopic Dermatitis (SCORAD) at Week 12

End point description:

The scoring of atopic dermatitis (SCORAD) is a clinical tool for assessing the severity (that is, extent, intensity) of atopic dermatitis (AD). The tool evaluates the extent and intensity of the AD lesions, along with participant symptoms. The range of the SCORAD is 0-103, where 0 indicates no eczema. The higher values indicating more severe disease. ITT population included all participants who were randomized and received any study investigational product. Here, "n" is number of participants analysed for this time point.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 12

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	55		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=56, 55)	58.66 (± 13.32)	57.68 (± 14.80)		
Week 12 (n=50, 49)	-19.35 (± 17.49)	-24.24 (± 16.94)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving >= 50% Reduction From Baseline in SCORAD 50

End point title	Percentage of Participants Achieving >= 50% Reduction From Baseline in SCORAD 50

End point description:

The SCORAD is a clinical tool for assessing the severity (that is, extent, intensity) of atopic dermatitis (AD). The tool evaluates the extent and intensity of the AD lesions, along with participant symptoms. The range of the SCORAD is 0-103, where 0 indicates no eczema. The higher values indicating more severe disease. The SCORAD 50 responder defined as a participant who achieves at least a 50% reduction in SCORAD score from baseline. ITT population included all participants who were randomized and received any study investigational product.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	55		
Units: Percentage of particpants				
number (not applicable)	29.4	41.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving >= 75% Reduction From Baseline in SCORAD 75

End point title	Percentage of Participants Achieving >= 75% Reduction From Baseline in SCORAD 75

End point description:

The SCORAD is a clinical tool for assessing the severity (that is, extent, intensity) of atopic dermatitis (AD). The tool evaluates the extent and intensity of the AD lesions, along with participant symptoms. The range of the SCORAD is 0-103, where 0 indicates no eczema. The higher values indicating more severe disease. The SCORAD 75 responder is defined as a participant who achieves at least a 75% reduction in SCORAD score from baseline. ITT population included all participants who were randomized and received any study investigational product.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	55		
Units: Percentage of particpants				
number (not applicable)	7.4	9.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in Average Pruritus Numeric Rating Scale (NRS) at Week 12

End point title	Mean Change from Baseline in Average Pruritus Numeric Rating Scale (NRS) at Week 12

End point description:

Pruritus is assessed using an Numeric Rating Scale (NRS) (0 - 10) with 0= no itch and 10= worst imaginable itch. Daily pruritus assessments were summarized as weekly peak score and a change from baseline in weekly peak score was calculated. ITT population included all participants who were randomized and received any study investigational product. Here, "n" is number of participants analysed for this time point.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 12

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	55		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=55, 55)	5.15 (± 2.10)	5.26 (± 2.02)		
Week 12 (n=48, 47)	-1.39 (± 1.93)	-1.90 (± 1.99)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in 5-D Pruritus Score at Week 12

End point title	Mean Change from Baseline in 5-D Pruritus Score at Week 12

End point description:

The 5-D pruritus scale is a brief questionnaire designed to assess itch. This scale takes into account the multidimensional nature of pruritus, its impact on quality of life, and is capable of detecting change over time. The 5-D pruritus scale included 5 domains (duration, degree, direction, disability, and distribution of pruritus). The total 5-D score was obtained by scoring each of the domains separately and then summing them together. 5-D total scores ranged between 5 (no pruritus) and 25 (most severe pruritus). The higher values indicating more severe pruritus. ITT population included all participants who were randomized and received any study investigational product. Here, "n" is number of participants analysed for this time point.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 12

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56	55		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n=52, 50)	16.7 (± 3.7)	16.0 (± 3.7)		
Week 12 (n=47, 46)	-3.9 (± 4.5)	-3.6 (± 4.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) and Treatment-Emergent Serious Adverse Events (TESAEs)

End point title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs) and Treatment-Emergent Serious Adverse Events (TESAEs)[1]

End point description:

An AE is any unfavourable and unintended signs, symptoms, or diseases temporally associated with use of study drug, whether or not considered related to study drug. SAE is any AE that resulted in death, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, life-threatening , a congenital anomaly/birth defect, or an important medical event. TEAEs are defined as AEs present at baseline that worsened in intensity after administration of study drug, or events absent at baseline that emerged after administration of study drug until Week 22. As-treated population included all participants who received any study drug. Participants who received at least one dose of MEDI9929 during the study, regardless of randomized treatment assignment, were analyzed under MEDI9929 group. One participant who randomized to placebo group but received an incorrect first dose of MEDI9929 was included in the "MEDI9929" group.

End point type	Secondary

End point timeframe:

From treatment administration (Day1) to 22 weeks

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: Statistical analysis was not applicable since there were no inferential statistics, only descriptive statistics were performed.

End point values	Placebo	MEDI9929 280mg		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	55	56		
Units: Number of particpants				
TEAEs	40	38		
TESAEs	3	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Trough Serum Concentration of MEDI9929

End point title	Mean Trough Serum Concentration of MEDI9929[2]

End point description:

The mean serum concentrations of MEDI9929 was observed. PK population included all participants who received MEDI9929 and had a sufficient number of serum concentration measurements for computing PK parameters. Here, "N" is number of participants analysed for this end point.

End point type	Secondary

End point timeframe:

Week 0 (Pre dose) and Week 12 (post dose)

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: Pharmacokinetic parameters were not analysed for placebo arm.

End point values	MEDI9929 280 mg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: mcg/mL				
arithmetic mean (standard deviation)	54.9 (± 21.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who Developed Detectable MEDI9929 Anti-drug Antibodies at Week 22

End point title	Number of Participants who Developed Detectable MEDI9929 Anti-drug Antibodies at Week 22

End point description:

A participant was considered ADA-positive across the study if they had a positive reading (titer of 50 or higher) at any time point during the study period. ITT population included all participants who were randomized and received any study investigational product. Here, "N" is the number of participants analysed for this end point.

End point type	Secondary

End point timeframe:

Baseline (Day 1) to Week 22

End point values	Placebo	MEDI9929 280 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	48		
Units: Number of particpants	2	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From treatment administration (Day1) to 22 weeks

Adverse event reporting additional description:

AEs were reported for As-treated population, which included all participants who received any study drug. Participants who received at least one dose of MEDI9929, regardless of randomized treatment, were analyzed under MEDI9929. One participant who randomized to placebo but received an incorrect first dose of MEDI9929 was included in MEDI9929 group

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	MEDI9929 280 mg

Reporting group description:

Participants received 6 subcutaneous doses of MEDI9929 280 mg every 2 weeks for 12 weeks, with the last dose at Week 10.

Reporting group title	Placebo

Reporting group description:

Participants received 6 subcutaneous doses of placebo every 2 weeks for 12 weeks, with the last dose at Week 10.

Serious adverse events	MEDI9929 280 mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 56 (3.57%)	3 / 55 (5.45%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 56 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			

subjects affected / exposed	1 / 56 (1.79%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected dermal cyst			
subjects affected / exposed	1 / 56 (1.79%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	MEDI9929 280 mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 56 (51.79%)	33 / 55 (60.00%)	
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 56 (5.36%)	1 / 55 (1.82%)	
occurrences (all)	4	1	
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	2 / 56 (3.57%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Injection site erythema			
subjects affected / exposed	3 / 56 (5.36%)	0 / 55 (0.00%)	
occurrences (all)	3	0	
Immune system disorders			
Food allergy			
subjects affected / exposed	2 / 56 (3.57%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	2 / 56 (3.57%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Diarrhoea			
subjects affected / exposed	5 / 56 (8.93%)	3 / 55 (5.45%)	
occurrences (all)	6	3	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	2 / 56 (3.57%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	5 / 56 (8.93%)	7 / 55 (12.73%)	
occurrences (all)	6	9	
Pruritus			
subjects affected / exposed	1 / 56 (1.79%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Rash			
subjects affected / exposed	0 / 56 (0.00%)	2 / 55 (3.64%)	
occurrences (all)	0	4	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 56 (1.79%)	2 / 55 (3.64%)	
occurrences (all)	1	2	
Muscle spasms			
subjects affected / exposed	1 / 56 (1.79%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Musculoskeletal pain			
subjects affected / exposed	2 / 56 (3.57%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Myalgia			
subjects affected / exposed	2 / 56 (3.57%)	0 / 55 (0.00%)	
occurrences (all)	2	0	
Infections and infestations			
Cellulitis			

subjects affected / exposed	0 / 56 (0.00%)	2 / 55 (3.64%)	
occurrences (all)	0	2	
Conjunctivitis			
subjects affected / exposed	1 / 56 (1.79%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Folliculitis			
subjects affected / exposed	1 / 56 (1.79%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Herpes simplex			
subjects affected / exposed	1 / 56 (1.79%)	1 / 55 (1.82%)	
occurrences (all)	1	1	
Nasopharyngitis			
subjects affected / exposed	13 / 56 (23.21%)	11 / 55 (20.00%)	
occurrences (all)	15	14	
Sinusitis			
subjects affected / exposed	2 / 56 (3.57%)	2 / 55 (3.64%)	
occurrences (all)	2	2	
Upper respiratory tract infection			
subjects affected / exposed	1 / 56 (1.79%)	7 / 55 (12.73%)	
occurrences (all)	1	8	
Urinary tract infection			
subjects affected / exposed	1 / 56 (1.79%)	1 / 55 (1.82%)	
occurrences (all)	1	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 September 2015	The Protocol was amended to modify the wording for the primary endpoint, secondary endpoints (1, 3, 5, and 6) and exploratory endpoints (1 and 2); Measurement of EASI50 was also added under the secondary endpoints as this endpoint were measured beyond Week 12; Removed "IgE" from the list of biomarkers; A positive QFT-G test for TB does not require an investigator's opinion; Added creatine kinase (CK) and lactate dehydrogenase (LDH) to the list of serum chemistry tests; Added the correct pruritus NRS instead of the incorrectly added eczema-related sleep NRS. Updated the text wherever applicable for more clarification.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported