Clinical trial results:
A Phase 2 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI9929 in Adult Subjects with Inadequately Controlled, Severe Asthma

Summary

EudraCT number	2013-003269-33
Trial protocol	HU CZ LT LV SK BG
Global end of trial date	01 March 2017

Results information

Result version number	v1 (current)
This version publication date	17 June 2018
First version publication date	17 June 2018

Trial information

Trial identification

Sponsor protocol code	CD-RI-MEDI9929-1146

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02054130
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedImmune, LLC
Sponsor organisation address	One MedImmune Way, Gaithersburg, Maryland, United States, 20878
Public contact	Fred Reid, MBChB, MedImmune, LLC, +44 0 203 749 6512, information.center@astrazeneca.com
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 March 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of 3 dose levels of MEDI9929 on asthma exacerbations in adult subjects with inadequately controlled, severe asthma

Protection of trial subjects:

The conduct of this study met all the local legal and regulatory requirements. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and was consistent with the ICH guidelines on GCP. Participating participants signed the 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:

In this study, all participants received stable background asthma therapy of medium- or high-dose inhaled corticosteroids (ICS) and long acting β2 agonist (LABA), with or without additional asthma controller medications that is consistent with Global Initiative for Asthma (GINA).

Evidence for comparator: -

Actual start date of recruitment	19 December 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 36
Country: Number of subjects enrolled	Slovakia: 75
Country: Number of subjects enrolled	Bulgaria: 57
Country: Number of subjects enrolled	Czech Republic: 44
Country: Number of subjects enrolled	Hungary: 95
Country: Number of subjects enrolled	Israel: 29
Country: Number of subjects enrolled	Japan: 19
Country: Number of subjects enrolled	Latvia: 36
Country: Number of subjects enrolled	Lithuania: 13
Country: Number of subjects enrolled	Serbia: 4
Country: Number of subjects enrolled	South Africa: 7
Country: Number of subjects enrolled	Ukraine: 135
Worldwide total number of subjects	550
EEA total number of subjects	320

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)	471
From 65 to 84 years	79
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted from 19Dec2013 to 01Mar2017 across 12 countries (United States, Slovakia, Bulgaria, Czech Republic, Hungary, Israel, Japan, Latvia, Lithuania, Serbia, South Africa, and Ukraine). A total of 918 participants were recruited in the study.

Pre-assignment

Screening details:

Of 918 participants, 334 were considered screen failures and 584 participants were randomized. Of which, all populations excluded 34 participants from one site due to non-compliance of the principles of Good Clinical Practice.

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, Monitor, Carer

Blinding implementation details:

This was a double-blind study. Neither the participant/legal representative nor any of the investigator or sponsor staff who are involved in the treatment or clinical evaluation of the participant were aware of the treatment received.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received 3 subcutaneous (SC) injections (1 × 1 mL and 2 × 1.5 mL) of placebo matched to MEDI9929 once every 2 weeks from Week 0, Day 1 to Week 50.

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

Dosage and administration details:

Participants received 3 subcutaneous (SC) injections (1 × 1 mL and 2 × 1.5 mL) of placebo matched to MEDI9929 once every 2 weeks from Week 0, Day 1 to Week 50.

Arm title	MEDI9929 70 mg

Arm description:

Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL placebo) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 70 milligram (mg) dose.

Arm type	Experimental
Investigational medicinal product name	MEDI9929 70 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL placebo) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 70 milligram (mg) dose.

Arm title	MEDI9929 210 mg

Arm description:

Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL [combining 1 mL MEDI9929 and 0.5 mL placebo in each syringe]) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 210 mg dose.

Arm type	Experimental
Investigational medicinal product name	MEDI9929 210 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL [combining 1 mL MEDI9929 and 0.5 mL placebo in each syringe]) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 210 mg dose.

Arm title	MEDI9929 280 mg

Arm description:

Participants received 3 SC injections (1 × 1 mL and 2 × 1.5 mL) of MEDI9929 280 mg dose once every 2 weeks from Week 0, Day 1 to Week 50.

Arm type	Experimental
Investigational medicinal product name	MEDI9929 280 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 3 SC injections (1 × 1 mL and 2 × 1.5 mL) of MEDI9929 280 mg dose once every 2 weeks from Week 0, Day 1 to Week 50.

Number of subjects in period 1	Placebo	MEDI9929 70 mg	MEDI9929 210 mg
Started	138	138	137
Completed	130	127	122
Not completed	8	11	15
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	4	4	7
Missed dose	4	6	7
Lost to follow-up	-	-	1

Number of subjects in period 1	MEDI9929 280 mg
Started	137
Completed	115
Not completed	22
Adverse event, serious fatal	-
Consent withdrawn by subject	10
Missed dose	10

Lost to follow-up	2

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received 3 subcutaneous (SC) injections (1 × 1 mL and 2 × 1.5 mL) of placebo matched to MEDI9929 once every 2 weeks from Week 0, Day 1 to Week 50.	
Reporting group title	MEDI9929 70 mg
Reporting group description:	
Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL placebo) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 70 milligram (mg) dose.	
Reporting group title	MEDI9929 210 mg
Reporting group description:	
Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL [combining 1 mL MEDI9929 and 0.5 mL placebo in each syringe]) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 210 mg dose.	
Reporting group title	MEDI9929 280 mg
Reporting group description:	
Participants received 3 SC injections (1 × 1 mL and 2 × 1.5 mL) of MEDI9929 280 mg dose once every 2 weeks from Week 0, Day 1 to Week 50.	

Reporting group values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg
Number of subjects	138	138	137
Age categorical Units: Subjects			
Adults (18-64 years)	118	117	114
From 65-84 years	20	21	23
Age Continuous Units: Years			
arithmetic mean	52.32	50.80	52.66
standard deviation	± 11.71	± 12.36	± 12.67
Sex: Female, Male Units: Subjects			
Male	44	49	50
Female	94	89	87
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	137	138	136
Unknown or Not Reported	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Asian|	6	3	5
Black or African American|	6	4	3
White|	123	131	128
Other|	2	0	0
Multiple Categories Checked|	1	0	1

Reporting group values	MEDI9929 280 mg	Total	

Number of subjects	137	550	
Age categorical Units: Subjects			
Adults (18-64 years)	122	471	
From 65-84 years	15	79	
Age Continuous Units: Years			
arithmetic mean	50.43		
standard deviation	± 12.25	-	
Sex: Female, Male Units: Subjects			
Male	46	189	
Female	91	361	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	4	
Not Hispanic or Latino	135	546	
Unknown or Not Reported	0	0	
Race/Ethnicity, Customized Units: Subjects			
Asian|	5	19	
Black or African American|	6	19	
White|	122	504	
Other|	2	4	
Multiple Categories Checked|	2	4	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received 3 subcutaneous (SC) injections (1 × 1 mL and 2 × 1.5 mL) of placebo matched to MEDI9929 once every 2 weeks from Week 0, Day 1 to Week 50.	
Reporting group title	MEDI9929 70 mg
Reporting group description:	
Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL placebo) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 70 milligram (mg) dose.	
Reporting group title	MEDI9929 210 mg
Reporting group description:	
Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL [combining 1 mL MEDI9929 and 0.5 mL placebo in each syringe]) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 210 mg dose.	
Reporting group title	MEDI9929 280 mg
Reporting group description:	
Participants received 3 SC injections (1 × 1 mL and 2 × 1.5 mL) of MEDI9929 280 mg dose once every 2 weeks from Week 0, Day 1 to Week 50.	

Primary: Annualized asthma exacerbation rate (AER) through Week 52

End point title	Annualized asthma exacerbation rate (AER) through Week 52
End point description:	
Asthma exacerbation is defined as worsening of asthma that leads to any of the following: use of systemic corticosteroids for at least 3 days, an emergency department visit due to asthma that required systemic corticosteroids, and an inpatient hospitalization due to asthma. The annual AER was presented as the total number of exacerbations for the treatment group divided by the total duration of person follow-up. Intent-to-treat (ITT) population was considered for this endpoint, which included all participants who are randomized and received any study drug.	
End point type	Primary
End point timeframe:	
Week 0 (Day 1) up to Week 52	

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: events per person-year				
number (confidence interval 95%)	0.72 (0.59 to 0.88)	0.27 (0.19 to 0.38)	0.20 (0.13 to 0.30)	0.23 (0.16 to 0.34)

Statistical analyses

Statistical analysis title	Comparison between Placebo and MEDI9929 70 mg
Comparison groups	MEDI9929 70 mg v Placebo
Number of subjects included in analysis	276
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.23
upper limit	0.63

Statistical analysis title	Comparison between Placebo and MEDI9929 210 mg
Comparison groups	Placebo v MEDI9929 210 mg
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Negative binomial regression
Parameter estimate	Rate ratio
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	0.51

Statistical analysis title	Comparison between Placebo and MEDI9929 280 mg
Comparison groups	Placebo v MEDI9929 280 mg
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Negative bnomial regression
Parameter estimate	Rate ratio
Point estimate	0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2
upper limit	0.58

Secondary: Reduction in AER on Subpopulations at Week 52

End point title	Reduction in AER on Subpopulations at Week 52

End point description:

Asthma exacerbation is defined as worsening of asthma that leads to any of the following: use of systemic corticosteroids for at least 3 days, an emergency department visit due to asthma that required systemic corticosteroids, and an inpatient hospitalization due to asthma. Reduction in AER was evaluated in pre-specified subpopulations of asthma. The annual AER was presented as the total number of exacerbations for the treatment group divided by the total duration of person follow-up. Also, the high or low was determined using median value. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug. The 'n' denotes the number of participants analysed for specified time points.

End point type	Secondary

End point timeframe:

Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: events per person-year				
number (confidence interval 95%)				
Eosinophilic->= 250 cells/µL (n=78,80,76,76)	0.78 (0.59 to 1.00)	0.29 (0.18 to 0.43)	0.26 (0.16 to 0.42)	0.21 (0.12 to 0.35)
Non-Eosinophilic- < 250 cells/µL(n=60,58,61,61)	0.65 (0.46 to 0.89)	0.25 (0.14 to 0.42)	0.14 (0.06 to 0.27)	0.26 (0.14 to 0.43)
Th2 Status - High (n=75,62,65,62)	0.62 (0.45 to 0.83)	0.33 (0.20 to 0.50)	0.25 (0.14 to 0.41)	0.21 (0.11 to 0.36)
Th2 Status - Low (n=62,75,70,74)	0.86 (0.64 to 1.13)	0.23 (0.14 to 0.37)	0.15 (0.07 to 0.28)	0.26 (0.15 to 0.41)
FENO - High (n=70,72,68,64)	0.94 (0.72 to 1.20)	0.32 (0.20 to 0.48)	0.20 (0.11 to 0.35)	0.20 (0.10 to 0.35)
FENO - Low (n=67,65,67,69)	0.51 (0.36 to 0.72)	0.23 (0.13 to 0.38)	0.21 (0.11 to 0.36)	0.28 (0.16 to 0.44)
Serum Periostin - High (n=69,63,73,68)	0.78 (0.59 to 1.02)	0.29 (0.17 to 0.45)	0.19 (0.10 to 0.33)	0.19 (0.10 to 0.32)
Serum Periostin - Low (n=69,74,63,66)	0.66 (0.48 to 0.89)	0.27 (0.16 to 0.42)	0.22 (0.12 to 0.38)	0.30 (0.18 to 0.47)
Post-BD FEV1 Reversibility-Yes (n=126,123,114,125)	0.60 (0.47 to 0.75)	0.26 (0.18 to 0.37)	0.17 (0.10 to 0.27)	0.21 (0.14 to 0.32)
Allergic (n=80,68,77,71)	0.75 (0.57 to 0.97)	0.25 (0.15 to 0.40)	0.14 (0.07 to 0.26)	0.23 (0.13 to 0.38)
Non-Allergic (n=50,60,50,58)	0.65 (0.44 to 0.91)	0.23 (0.12 to 0.39)	0.26 (0.13 to 0.45)	0.22 (0.11 to 0.38)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Pre-bronchodilator (pre-BD) Forced Expiratory Volume in 1 second (FEV1) and Forced Vital Capacity (FVC) at Week 52

End point title	Change From Baseline in Pre-bronchodilator (pre-BD) Forced Expiratory Volume in 1 second (FEV1) and Forced Vital Capacity (FVC) at Week 52

End point description:

Forced expiratory volume in 1 second and forced vital capacity measures taken before bronchodilator use were reported. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug. The 'n' denotes the number of participants analysed for specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 0 [Day 1]) to Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Liter				
arithmetic mean (standard deviation)				
Pre-BD FEV1(n=131,130,121,116)	0.071 (± 0.405)	0.200 (± 0.432)	0.210 (± 0.433)	0.245 (± 0.411)
Pre-BD FVC (n=131,130,121,116)	0.068 (± 0.477)	0.244 (± 0.560)	0.202 (± 0.616)	0.197 (± 0.484)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in FEV1 on Subpopulations at Week 52

End point title	Change From Baseline in FEV1 on Subpopulations at Week 52

End point description:

Forced expiratory volume in one second (FEV1) was evaluated in pre-specified subpopulations of asthma. The data presented in the below table for this OM is for Pre-BD FEV1. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug. The 'n' denotes the number of participants analysed for specified time points. The dispersion measure (standard deviation) was only generated for the outcome measures relative to placebo. Therefore, reported by an arbitrary value (99999).

End point type	Secondary

End point timeframe:

Baseline and up to Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Liters				
least squares mean (standard deviation)				
Eosinophilic- >= 250 cells/µL (n=76,77,66,63)	-0.045 (± 99999)	0.118 (± 99999)	0.125 (± 99999)	0.160 (± 99999)
Non-Eosinophilic- < 250 cells/µL (n=55,53,55,53)	-0.072 (± 99999)	-0.030 (± 99999)	0.008 (± 99999)	0.011 (± 99999)
Th2 Status – High |(n=73,59,57,53)	-0.058 (± 99999)	0.037 (± 99999)	0.052 (± 99999)	0.182 (± 99999)
Th2 Status – Low |(n=57,70,62,62)	-0.052 (± 99999)	0.103 (± 99999)	0.103 (± 99999)	0.062 (± 99999)
FENO – High (n=65,66,60,54)	-0.054 (± 99999)	0.093 (± 99999)	0.137 (± 99999)	0.155 (± 99999)
FENO – Low |(n=65,63,59,59)	0.027 (± 99999)	0.115 (± 99999)	0.095 (± 99999)	0.133 (± 99999)
Serum Periostin – High (n=67,61,65,61)	-0.017 (± 99999)	0.147 (± 99999)	0.207 (± 99999)	0.185 (± 99999)
Serum Periostin – Low (n=64,68,55,52)	-0.040 (± 99999)	0.060 (± 99999)	-0.013 (± 99999)	0.064 (± 99999)
Post-BD FEV1 Reversibility-Yes (n=120,117,102,105)	-0.081 (± 99999)	0.052 (± 99999)	0.049 (± 99999)	0.066 (± 99999)
Allergic (n=75,65,70,57)	-0.047 (± 99999)	0.131 (± 99999)	0.084 (± 99999)	0.065 (± 99999)
Non-Allergic (n=48,56,42,52)	-0.037 (± 99999)	0.050 (± 99999)	0.148 (± 99999)	0.164 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Post-bronchodilator (post-BD) FEV1 and FVC at Week 52

End point title	Change From Baseline in Post-bronchodilator (post-BD) FEV1 and FVC at Week 52

End point description:

Forced expiratory volume in 1 second and forced vital capacity measures taken after bronchodilator use were reported. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug. The 'n' denotes the number of participants analysed for specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 0 [Day 1]) to Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Liter				
arithmetic mean (standard deviation)				
Post-BD FEV1 (n=130,130,121,115)	-0.064 (± 0.352)	0.117 (± 0.389)	0.099 (± 0.449)	0.128 (± 0.415)
Post-BD FVC (n=130,130,121,115)	-0.092 (± 0.353)	0.088 (± 0.439)	0.092 (± 0.515)	0.083 (± 0.435)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Overall Symptoms Score on Subpopulations at Week 52

End point title	Change From Baseline in Overall Symptoms Score on Subpopulations at Week 52

End point description:

The overall asthma symptom score is the average of scores of day time severity, day time frequency, and night time severity. Overall asthma symptom score was evaluated in pre-specified subpopulations of asthma. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug. The 'n' denotes the number of participants analysed for specified time points. The dispersion measure was only generated for the outcome measures relative to placebo. Therefore, reported by an arbitrary value (99999).

End point type	Secondary

End point timeframe:

Baseline and up to Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Units on a scale				
least squares mean (standard deviation)				
Eosinophilic- >= 250 cells/µL (n=70,72,58,64)	-0.57 (± 99999)	-0.62 (± 99999)	-0.78 (± 99999)	-0.72 (± 99999)
Non-Eosinophilic- < 250 cells/µL (n=48,47,47,49)	-0.49 (± 99999)	-0.60 (± 99999)	-0.56 (± 99999)	-0.72 (± 99999)
Th2 Status - High (n=65,54,51,48)	-0.54 (± 99999)	-0.65 (± 99999)	-0.62 (± 99999)	-0.75 (± 99999)
Th2 Status - Low (n=52,64,52,54)	-0.50 (± 99999)	-0.57 (± 99999)	-0.72 (± 99999)	-0.71 (± 99999)
FENO - High (n=59,60,49,44)	-0.52 (± 99999)	-0.68 (± 99999)	-0.75 (± 99999)	-0.72 (± 99999)
FENO - Low (n=59,58,54,56)	-0.54 (± 99999)	-0.55 (± 99999)	-0.59 (± 99999)	-0.71 (± 99999)
Serum Periostin - High (n=63,57,56,54)	-0.48 (± 99999)	-0.54 (± 99999)	-0.84 (± 99999)	-0.74 (± 99999)
Serum Periostin - Low (n=55,61,48,46)	-0.58 (± 99999)	-0.63 (± 99999)	-0.47 (± 99999)	-0.69 (± 99999)

Post-BD FEV1 Reversibility-Yes(n=108,106,87,92)	-0.55 (± 99999)	-0.60 (± 99999)	-0.64 (± 99999)	-0.71 (± 99999)
Allergic (n=66,56,60,48)	-0.53 (± 99999)	-0.59 (± 99999)	-0.63 (± 99999)	-0.67 (± 99999)
Non-Allergic (n=46,55,36,47)	-0.50 (± 99999)	-0.60 (± 99999)	-0.72 (± 99999)	-0.85 (± 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Asthma Symptoms Measured by Asthma Daily Diary at Week 52

End point title	Change From Baseline in Asthma Symptoms Measured by Asthma Daily Diary at Week 52

End point description:

The asthma daily diary includes the following daily assessments: asthma symptoms; inhalations of rescue medication; night time awakening due to asthma requiring rescue medication use, asthma-related activity limitations, asthma-related stress, and background medication compliance. It was measured as daytime severity, daytime frequency, and nightime severity. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug.

End point type	Secondary

End point timeframe:

Baseline (Week 0 [Day 1]) and Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	118	119	105	103
Units: Units on a scale				
arithmetic mean (standard deviation)				
Daytime Severity	-0.483 (± 0.700)	-0.657 (± 0.726)	-0.669 (± 0.640)	-0.680 (± 0.688)
Daytime Frequency	-0.493 (± 0.792)	-0.598 (± 0.837)	-0.727 (± 0.753)	-0.754 (± 0.752)
Nighttime Severity	-0.643 (± 0.799)	-0.616 (± 0.687)	-0.807 (± 0.699)	-0.662 (± 0.730)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Asthma symptoms measured by Asthma Control Questionnaire (ACQ-6) Score at Week 52

End point title	Change From Baseline in Asthma symptoms measured by Asthma Control Questionnaire (ACQ-6) Score at Week 52

End point description:

The ACQ is a patient-reported questionnaire assessing asthma symptoms (ie, night-time waking, symptoms on waking, activity limitation, shortness of breath, wheezing) and daily rescue bronchodilator

use and FEV1. The ACQ-6 is a shortened version of the ACQ that omits the FEV1 measurement from the original ACQ score. Questions are weighted equally and scored from 0 (totally controlled) to 6 (severely uncontrolled). ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug.

End point type	Secondary

End point timeframe:

Baseline (Week 0 [Day 1]) and Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	44	49
Units: Units on a scale				
arithmetic mean (standard deviation)	-0.89 (± 0.91)	-1.24 (± 0.94)	-1.17 (± 1.00)	-1.19 (± 1.00)

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of Severe Asthma Exacerbation Through Week 52

End point title	Rate of Severe Asthma Exacerbation Through Week 52

End point description:

A severe asthma exacerbation is defined as an event that resulted in hospitalization. The severe AER was presented as the total number of exacerbations for the treatment group divided by the total duration of person follow-up. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug.

End point type	Secondary

End point timeframe:

Week 0 (Day 1) up to Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: events per person-year				
number (confidence interval 95%)	0.14 (0.08 to 0.22)	0.04 (0.01 to 0.09)	0.02 (0.00 to 0.07)	0.03 (0.01 to 0.08)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Asthma Exacerbation Through Week 52

End point title	Time to First Asthma Exacerbation Through Week 52

End point description:

Asthma exacerbation is defined as worsening of asthma that leads to use of systemic corticosteroids for at least 3 days, an emergency department visit due to asthma that required systemic corticosteroids, and an inpatient hospitalization due to asthma. Time to first asthma exacerbation was reported. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug. Median time was not estimable due to less than 50% participants had exacerbations occurred. Therefore, reported with arbitrary values (99999).

End point type	Secondary

End point timeframe:

Week 0 (Day 1) through Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

Statistical analyses

Statistical analysis title	Comparison between Placebo and MEDI9929 70 mg
Comparison groups	Placebo v MEDI9929 70 mg
Number of subjects included in analysis	276
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.044
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	0.99

Statistical analysis title	Comparison between Placebo and MEDI9929 210 mg
Comparison groups	Placebo v MEDI9929 210 mg
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.002
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	0.75

Statistical analysis title	Comparison between Placebo and MEDI9929 280 mg
Comparison groups	Placebo v MEDI9929 280 mg
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.013
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	0.88

Secondary: Time to First Severe Asthma Exacerbation Through Week 52

End point title	Time to First Severe Asthma Exacerbation Through Week 52

End point description:

Asthma exacerbation is defined as worsening of asthma that leads to use of systemic corticosteroids for at least 3 days, an emergency department visit due to asthma that required systemic corticosteroids, and an inpatient hospitalization due to asthma. Time to first severe asthma exacerbations (hospitalization) were reported. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug. Median time was not estimable due to less than 50% participants had exacerbations occurred. Therefore, reported with arbitrary values (99999).

End point type	Secondary

End point timeframe:

Week 0 (Day 1) through Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

Statistical analyses

Statistical analysis title	Comparison between Placebo and MEDI9929 70 mg
Comparison groups	Placebo v MEDI9929 70 mg
Number of subjects included in analysis	276
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.231
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.17
upper limit	1.52

Statistical analysis title	Comparison between Placebo and MEDI9929 210 mg
Comparison groups	Placebo v MEDI9929 210 mg
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.077
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	1.21

Statistical analysis title	Comparison between Placebo and MEDI9929 280 mg
Comparison groups	Placebo v MEDI9929 280 mg
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.151
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.14
upper limit	1.43

Secondary: Number of Participants With at least one Asthma Exacerbations Through Week 52

End point title	Number of Participants With at least one Asthma Exacerbations Through Week 52

End point description:

Asthma exacerbation is defined as worsening of asthma that leads to use of systemic corticosteroids for at least 3 days, an emergency department visit due to asthma that required systemic corticosteroids, and an inpatient hospitalization due to asthma. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug.

End point type	Secondary

End point timeframe:

Week 0 (Day 1) through Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Participants	43	30	21	25

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With at least one Severe Asthma Exacerbations Through Week 52

End point title	Number of Participants With at least one Severe Asthma Exacerbations Through Week 52

End point description:

Asthma exacerbation is defined as worsening of asthma that leads to use of systemic corticosteroids for at least 3 days, an emergency department visit due to asthma that required systemic corticosteroids, and an inpatient hospitalization due to asthma. Participants with severe asthma exacerbations (hospitalization) were reported. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug.

End point type	Secondary

End point timeframe:

Week 0 (Day 1) through Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Participants	9	5	3	4

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Asthma Quality of Life Questionnaire (Standardized Version) (AQLQ [S]) Overall Score at Week 52

End point title	Change From Baseline in Asthma Quality of Life Questionnaire (Standardized Version) (AQLQ [S]) Overall Score at Week 52

End point description:

The AQLQ(S) +12 is a 32-item questionnaire that measures the health-related quality of life experienced by asthma participants. The questionnaire comprises 4 separate domains (symptoms, activity limitations, emotional function, and environmental stimuli) scaled on a 7-point scale ranging from 7 (no impairment) to 1 (severe impairment). ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug.

End point type	Secondary

End point timeframe:

Baseline (Week 0 [Day 1]) and Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	47	51	41	48
Units: Units on a scale				
arithmetic mean (standard deviation)	1.04 (± 1.11)	1.19 (± 0.90)	0.93 (± 1.03)	1.13 (± 1.13)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life-5 Dimensions 5 Level Version (EQ-5D-5L) Health State Evaluation at Week 52

End point title	Change From Baseline in European Quality of Life-5 Dimensions 5 Level Version (EQ-5D-5L) Health State Evaluation at Week 52

End point description:

The EQ-5D-5L questionnaire assesses 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 response options (no problems, slight problems, moderate problems, severe problems, and extreme problems) that reflect increasing levels of difficulty. The questionnaire also includes a visual analogue scale, where the participant will be asked to rate current health status on a scale of 0-100, with 0 being the worst imaginable health state. The health state valuation (an index-based value) and the visual analog scale were summarized. ITT population was considered for this endpoint, which included all participants who are randomized and received any study drug. The 'n' denotes the number of participants analysed for specified time points.

End point type	Secondary

End point timeframe:

Baseline (Week 0 [Day 1]) and Week 52

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Units on a scale				
arithmetic mean (standard deviation)				
Health State Valuation (n=38,41,33,40)	0.1051 (± 0.1511)	0.0752 (± 0.2179)	0.0729 (± 0.1624)	0.0395 (± 0.1935)
Visual Analog Scale (n=138,138,137,137)	13.8 (± 17.6)	14.0 (± 16.4)	12.0 (± 18.0)	12.3 (± 18.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Total amount of Study Drug Exposure

End point title	Total amount of Study Drug Exposure[1]

End point description:

The total amount of study drug exposure (in mg) for the entire study period was summarized. As-treated population was considered for this endpoint, which included all participants who received any study drug.

End point type	Secondary

End point timeframe:

Week 0 (Day 1) through Week 52

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	138	137	137	
Units: Milligram				
arithmetic mean (standard deviation)	877.0 (± 116.9)	2493.9 (± 640.4)	6574.9 (± 1630.2)	

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)

End point description:

An adverse event is any unfavourable and unintended signs (including abnormal laboratory findings), symptoms, or diseases temporally associated with use of medicinal product, whether or not considered related to medicinal product. Serious adverse event is any AE that resulted in death, life-threatening, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, is a congenital anomaly/birth defect in offspring of a study participant, is an important medical event that may jeopardize the participant or may require medical intervention. TEAEs are defined as events present at baseline that worsened in intensity after administration of study drug or events absent at baseline that emerged after administration of study drug, for the period until and including the follow-up period (Week 64). As-treated population was considered for this endpoint, which included all participants who received any study drug.

End point type	Secondary

End point timeframe:

Day 1 upto Week 64

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Participants				
TEAEs|	91	93	90	89
TESAEs|	18	17	13	18

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With TEAEs Related to Vital Sign Parameters

End point title	Number of Participants With TEAEs Related to Vital Sign Parameters

End point description:

AEs observed in participants with clinically significant vital signs abnormalities were assessed. As-treated population was considered for this endpoint, which included all participants who received any study drug.

End point type	Secondary

End point timeframe:

Day 1 upto Week 64

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Participants				
Blood pressure diastolic increased|	0	1	0	0
Blood pressure increased|	1	2	1	0
Heart rate increased|	0	0	0	1
Hypertension|	7	7	5	6
Hypertensive crisis|	0	0	0	1
Hypotension|	0	0	0	2
Pyrexia|	0	2	2	0
Respiratory rate increased|	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With TEAEs Related to Clinical Laboratory Evaluation

End point title	Number of Participants With TEAEs Related to Clinical Laboratory Evaluation

End point description:

An abnormal laboratory finding which required an action or intervention by the investigator, or a finding judged by the investigator to represent a change beyond the range of normal physiologic fluctuation were reported as an adverse event. Laboratory evaluations of blood and urine samples were performed. As-treated population was considered for this endpoint, which included all participants who received any study drug.

End point type	Secondary

End point timeframe:

Day 1 upto Week 64

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Participants				
Anaemia|	0	0	0	1
Leukopenia|	0	1	0	0
Lymphopenia|	0	1	0	0
Neutropenia|	0	1	0	0
Thrombocytopenia|	0	1	0	0
Dyslipidaemia|	0	1	0	0
Hepatic enzyme increased|	0	0	1	0
Hypercholesterolaemia|	0	0	1	0
Hyperuricaemia|	0	0	1	0
Hypokalaemia|	0	0	1	0
Vitamin D deficiency|	0	0	1	0
Hematuria|	1	0	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With TEAEs Related to Electrocardiogram Evaluations

End point title	Number of Participants With TEAEs Related to Electrocardiogram Evaluations

End point description:

AEs observed in participants with clinically significant ECG abnormalities were assessed. As-treated population was considered for this endpoint, which included all participants who received any study drug.

End point type	Secondary

End point timeframe:

From the start of study drug administration upto Week 64

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Participants				
Atrial fibrillation|	1	0	2	0
Atrial flutter|	0	1	0	0
Bundle branch block left|	0	0	1	0
Supraventricular extrasystoles|	1	0	0	0
Tachycardia|	1	1	1	2

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Serum Concentrations of MEDI9929

End point title	Mean Serum Concentrations of MEDI9929[2]

End point description:

The mean serum concentrations of MEDI9929 was observed at specified timepoints. Pharmacokinetic population was considered for this endpoint, which included all participants who received MEDI9929 and have a sufficient number of serum concentration measurements. The 'n' denotes the number of participants analysed for specified time points.

End point type	Secondary

End point timeframe:

Weeks 4, 12, 20, 28, 40, 52, and 64

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	133	128	132	
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 4 (n=129,126,130)	3933.6 (± 3022.7)	10733.1 (± 4649.4)	39722.7 (± 15140.7)	
Week 12 (n=129,121,126)	6215.8 (± 3779.2)	16625.4 (± 7751.6)	63223.7 (± 60627.6)	
Week 20 (n=126,113,116)	6028.3 (± 2897.9)	18237.1 (± 8721.9)	64442.9 (± 22558.3)	
Week 28 (n=127,117,120)	6084.1 (± 2885.5)	19373.4 (± 9191.4)	64659.9 (± 24121.6)	
Week 40 (n=127,117,118)	6050.4 (± 3296.4)	18926.1 (± 10252.7)	64404.0 (± 26473.0)	
Week 52 (n=128,118,116)	6027.2 (± 3024.8)	18821.9 (± 10435.2)	68899.1 (± 71137.2)	
Week 64 (n=123,116,113)	632.8 (± 519.5)	1991.2 (± 1882.4)	6986.0 (± 5289.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive Antibodies to MEDI9929

End point title	Number of Participants With Positive Antibodies to MEDI9929

End point description:

Blood samples for immunogenicity assessment included the determination of anti-drug antibodies (ADA) for MEDI9929. The number of participants with positive serum antibodies to MEDI9929 were presented. As-treated population was considered for this endpoint, which included all participants who received any study drug. The 'n' denotes the number of participants analysed for specified time points.

End point type	Secondary

End point timeframe:

Week 0 (Day 1) to Week 64

End point values	Placebo	MEDI9929 70 mg	MEDI9929 210 mg	MEDI9929 280 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	138	138	137	137
Units: Participants				
ADA Positive at Baseline (n=138,137,136,135)	7	1	2	2
ADA prevalence (n=138,136,131,131)	13	6	2	4
ADA incidence (n=138,136,131,131)	13	5	1	3

NeutralizingAntibodyADAPositive(n=138,136,131,131)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From Day 1 upto Week 64	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received 3 subcutaneous (SC) injections (1 × 1 mL and 2 × 1.5 mL) of placebo matched to MEDI9929 once every 2 weeks from Week 0, Day 1 to Week 50.	
Reporting group title	MEDI9929 70 mg
Reporting group description:	
Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL placebo) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 70 milligram (mg) dose.	
Reporting group title	MEDI9929 210 mg
Reporting group description:	
Participants received 3 SC injections (1 × 1 mL MEDI9929 and 2 × 1.5 mL [combining 1 mL MEDI9929 and 0.5 mL placebo in each syringe]) once every 4 weeks from Week 0, Day 1 to Week 48 alternating with 3 SC injections (1 × 1 mL and 2 × 1.5 mL of placebo) once every 4 weeks from Week 2 to Week 50 equivalent to MEDI9929 210 mg dose.	
Reporting group title	MEDI9929 280 mg
Reporting group description:	
Participants received 3 SC injections (1 × 1 mL and 2 × 1.5 mL) of MEDI9929 280 mg dose once every 2 weeks from Week 0, Day 1 to Week 50.	

Serious adverse events	Placebo	MEDI9929 70 mg	MEDI9929 210 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 138 (13.04%)	17 / 138 (12.32%)	13 / 137 (9.49%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Basal cell carcinoma			

subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage i			
subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	0 / 137 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Pregnancy, puerperium and perinatal conditions			
Abortion threatened			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyperemesis gravidarum			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Reproductive system and breast disorders			
Cervical leukoplakia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Ovarian cyst			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Testicular pain			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	10 / 138 (7.25%)	5 / 138 (3.62%)	4 / 137 (2.92%)
occurrences causally related to treatment / all	0 / 23	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Injury, poisoning and procedural complications			
Cartilage injury			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Foreign body aspiration			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Lumbar vertebral fracture			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Post procedural complication			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Upper limb fracture			

subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	0 / 137 (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
Atrial flutter			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-barre syndrome			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			

subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	0 / 137 (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
Hiatus hernia			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Large intestine polyp			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Pancreatitis acute			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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 atopic			
subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	0 / 137 (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

Dermatitis contact			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
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			
Bronchitis			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Cellulitis			

subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	0 / 137 (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
Chronic sinusitis			
subjects affected / exposed	1 / 138 (0.72%)	1 / 138 (0.72%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Genitourinary tract infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	0 / 137 (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
Influenza			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Pneumonia			
subjects affected / exposed	1 / 138 (0.72%)	3 / 138 (2.17%)	0 / 137 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis chronic			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Sinusitis			
subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	0 / 137 (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
Staphylococcal infection			

subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	1 / 138 (0.72%)	0 / 138 (0.00%)	0 / 137 (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
Urinary tract infection			
subjects affected / exposed	0 / 138 (0.00%)	1 / 138 (0.72%)	0 / 137 (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
Viral infection			
subjects affected / exposed	0 / 138 (0.00%)	0 / 138 (0.00%)	1 / 137 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	MEDI9929 280 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 137 (13.14%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipoma			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Pancreatic carcinoma metastatic				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer stage i				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Deep vein thrombosis				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				
subjects affected / exposed	1 / 137 (0.73%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
Abortion threatened				
subjects affected / exposed	1 / 137 (0.73%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hyperemesis gravidarum				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Non-cardiac chest pain				

subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Cervical leukoplakia			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian cyst			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Testicular pain			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	6 / 137 (4.38%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Cartilage injury			

subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	1 / 137 (0.73%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foreign body aspiration				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament sprain				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar vertebral fracture				
subjects affected / exposed	1 / 137 (0.73%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural complication				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper limb fracture				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Atrial fibrillation				

subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervicobrachial syndrome			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Guillain-barre syndrome			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sciatica			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hiatus hernia			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestine polyp			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis contact			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteochondrosis			
subjects affected / exposed	1 / 137 (0.73%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rhabdomyolysis			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic sinusitis			

subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	1 / 137 (0.73%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Genitourinary tract infection				
subjects affected / exposed	1 / 137 (0.73%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	2 / 137 (1.46%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis chronic				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	0 / 137 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tooth abscess				

subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	0 / 137 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Placebo	MEDI9929 70 mg	MEDI9929 210 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	56 / 138 (40.58%)	49 / 138 (35.51%)	44 / 137 (32.12%)
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 138 (4.35%)	6 / 138 (4.35%)	11 / 137 (8.03%)
occurrences (all)	11	10	21
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	47 / 138 (34.06%)	31 / 138 (22.46%)	23 / 137 (16.79%)
occurrences (all)	111	50	37
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	16 / 138 (11.59%)	19 / 138 (13.77%)	19 / 137 (13.87%)
occurrences (all)	26	24	25
Bronchitis			
subjects affected / exposed	7 / 138 (5.07%)	7 / 138 (5.07%)	5 / 137 (3.65%)
occurrences (all)	11	7	6

Non-serious adverse events	MEDI9929 280 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 137 (36.50%)		

Nervous system disorders Headache subjects affected / exposed occurrences (all)	 5 / 137 (3.65%) 11		
Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all)	 35 / 137 (25.55%) 47		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Bronchitis subjects affected / exposed occurrences (all)	 15 / 137 (10.95%) 30 9 / 137 (6.57%) 11		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 October 2014	The original protocol was amended to modify several inclusion and exclusion criteria for ease of enrollment, to provide further clarification, and to correct typographical errors.
10 February 2016	The purpose of this amendment was to change the Medical Monitor of the study.
01 August 2016	The purpose of this amendment was to change the Medical Monitor of the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported