



Clinical trial results: Long-term Allopurinol Safety Study Evaluating Outcomes in Gout Patients (LASSO)

Summary

EudraCT number	2011-002453-65
Trial protocol	DE BE
Global end of trial date	01 January 2013

Results information

Result version number	v1 (current)
This version publication date	05 February 2017
First version publication date	05 February 2017

Trial information

Trial identification

Sponsor protocol code	ALLO-401
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01391325
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ardea Biosciences, Inc.
Sponsor organisation address	9390 Towne Centre Dr., San Diego, United States,
Public contact	Nihar Bhakta, Ardea Biosciences, Inc., +1 8586526671, nbhakta@ardeabio.com
Scientific contact	Nihar Bhakta, Ardea Biosciences, Inc., +1 8586526671, nbhakta@ardeabio.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 March 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 January 2013
Global end of trial reached?	Yes
Global end of trial date	01 January 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety of allopurinol at medically appropriate doses.

Protection of trial subjects:

This study was conducted in accordance with the protocol, International Conference on Harmonisation (ICH) E6 Good Clinical Practice (GCP), the Declaration of Helsinki (2008), and all other applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 June 2011
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: 1205
Country: Number of subjects enrolled	Canada: 75
Country: Number of subjects enrolled	Belgium: 11
Country: Number of subjects enrolled	Germany: 14
Country: Number of subjects enrolled	New Zealand: 84
Country: Number of subjects enrolled	Australia: 104
Country: Number of subjects enrolled	South Africa: 242
Worldwide total number of subjects	1735
EEA total number of subjects	25

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)	1486
From 65 to 84 years	249
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

1,735 subjects enrolled in the study; however, only 1,732 were treated. Therefore, 1,732 subjects started the treatment period.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Allopurinol
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Arm description:

Allopurinol: Commercially available allopurinol 100 mg and 300 mg oral tablets will be prescribed by the Investigator according to the approved product label.

Arm type	Treatment
Investigational medicinal product name	Allopurinol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg, 300 mg

Number of subjects in period 1 ^[1]	Allopurinol
Started	1732
Completed	1238
Not completed	494
Adverse event, serious fatal	2
Consent withdrawn by subject	79
Physician decision	67
Adverse event, non-fatal	69
Treatment Failure	35
Baseline sUA < 6.5 mg/dL	116
Sponsor Decision	7
Lost to follow-up	94
Gout Flare	3
Protocol deviation	22

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 1,735 subjects enrolled in the study; however, only 1,732 were treated. Therefore, 1,732 subjects started the treatment period.

Baseline characteristics

Reporting groups

Reporting group title	Allopurinol
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Reporting group description:

Allopurinol: Commercially available allopurinol 100 mg and 300 mg oral tablets will be prescribed by the Investigator according to the approved product label.

Reporting group values	Allopurinol	Total	
Number of subjects	1732	1732	
Age Categorical Units: participants			
<=18 years	0	0	
Between 18 and 65 years	1483	1483	
>=65 years	249	249	
Age Continuous Units: years			
arithmetic mean	51.4		
standard deviation	± 11.93	-	
Gender, Male/Female Units: participants			
Female	118	118	
Male	1614	1614	
Region of Enrollment Units: Subjects			
United States	1203	1203	
Canada	74	74	
Belgium	11	11	
Australia	104	104	
South Africa	242	242	
Germany	14	14	
New Zealand	84	84	

End points

End points reporting groups

Reporting group title	Allopurinol
Reporting group description: Allopurinol: Commercially available allopurinol 100 mg and 300 mg oral tablets will be prescribed by the Investigator according to the approved product label.	

Primary: Safety of allopurinol

End point title	Safety of allopurinol ^[1]
End point description: Proportion of subjects who experienced at least one Treatment Emergent Adverse Event (TEAE) during the study.	
End point type	Primary
End point timeframe: Every month for 6 months.	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: No statistical analysis provided for Safety of Allopurinol. .	

End point values	Allopurinol			
Subject group type	Reporting group			
Number of subjects analysed	1732			
Units: percentage of subjects				
number (not applicable)	55.1			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects with Serum urate (sUA) less than 6.0 mg/dL

End point title	Proportion of subjects with Serum urate (sUA) less than 6.0 mg/dL
End point description: Proportion of subjects with serum urate (sUA) less than 6.0 mg/dL at Month 6 using Last Observation Carried Forward (LOCF) for subjects with missing values at Month 6.	
End point type	Secondary
End point timeframe: Month 6	

End point values	Allopurinol			
Subject group type	Reporting group			
Number of subjects analysed	1732			
Units: percentage of subjects				
number (confidence interval 95%)	43.4 (41 to 46)			

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of gout flares

End point title	Incidence of gout flares
End point description: Proportion of subjects who experienced at least one gout flare requiring treatment during the study.	
End point type	Secondary
End point timeframe: Every month for 6 months.	

End point values	Allopurinol			
Subject group type	Reporting group			
Number of subjects analysed	1732			
Units: percentage of subjects				
number (confidence interval 95%)	33.4 (31 to 36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline to Month 6 in SF-36 PCS+MCS

End point title	Mean change from baseline to Month 6 in SF-36 PCS+MCS
End point description: The SF-36 is a short-form health survey with 36 questions that yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical (PCS) and mental health (MCS) summary. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability. The higher the score the less disability. The component scores (PCS and MCS) are norm-based to a standard population with a mean of 50 and a standard deviation of 10.	
End point type	Secondary
End point timeframe: Month 6	

End point values	Allopurinol			
Subject group type	Reporting group			
Number of subjects analysed	1732			
Units: units on a scale				
arithmetic mean (standard deviation)				
SF-36 Physical Component Summary	3.88 (± 8.458)			
SF-36 Mental Health Component Summary	0.71 (± 9.076)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

6 months

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MeDRA 14.0
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Dictionary version	14.0
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Reporting groups

Reporting group title	Allopurinol
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Reporting group description:

Treatment. Allopurinol: Commercially available allopurinol 100 mg and 300 mg oral tablets will be prescribed by the Investigator according to the approved product label.

Serious adverse events	Allopurinol		
Total subjects affected by serious adverse events			
subjects affected / exposed	52 / 1732 (3.00%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder cancer			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	2 / 1732 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Renal cell carcinoma			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombosis			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Epistaxis			

subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Bipolar I disorder			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breathing-related sleep disorder			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Panic disorder with agoraphobia			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood glucose increased			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic enzymes increased			

subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Foot fracture			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ligament rupture			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	2 / 1732 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			
subjects affected / exposed	3 / 1732 (0.17%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	2 / 1732 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	2 / 1732 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Cardiac failure acute			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery occlusion			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pericarditis constrictive			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	2 / 1732 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Convulsion			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic stroke			

subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colonic obstruction			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric haemorrhage			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	2 / 1732 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			

Biliary colic			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure acute			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Gouty arthritis			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

<p>Infections and infestations</p> <p>Abscess</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 1732 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p>		
<p>Abscess intestinal</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 1732 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p>		
<p>Abscess limb</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 1732 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p>		
<p>Cellulitis</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>2 / 1732 (0.12%)</p> <p>0 / 2</p> <p>0 / 0</p>		
<p>Cholecystitis infective</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 1732 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p>		
<p>Diverticulitis</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>2 / 1732 (0.12%)</p> <p>0 / 2</p> <p>0 / 0</p>		
<p>Gastroenteritis</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 1732 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p>		
<p>Meningitis viral</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 1732 (0.06%)</p> <p>0 / 1</p> <p>0 / 0</p>		
<p>Osteomyelitis</p>			

subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Perirectal abscess			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	3 / 1732 (0.17%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	2 / 1732 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lactic acidosis			

subjects affected / exposed	1 / 1732 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Allopurinol		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	654 / 1732 (37.76%)		
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	48 / 1732 (2.77%)		
occurrences (all)	70		
Alanine aminotransferase increased			
subjects affected / exposed	38 / 1732 (2.19%)		
occurrences (all)	45		
Aspartate aminotransferase increased			
subjects affected / exposed	23 / 1732 (1.33%)		
occurrences (all)	30		
Liver function test abnormal			
subjects affected / exposed	19 / 1732 (1.10%)		
occurrences (all)	23		
Injury, poisoning and procedural complications			
Muscle strain			
subjects affected / exposed	25 / 1732 (1.44%)		
occurrences (all)	34		
Vascular disorders			
Hypertension			
subjects affected / exposed	43 / 1732 (2.48%)		
occurrences (all)	45		
Nervous system disorders			
Headache			
subjects affected / exposed	41 / 1732 (2.37%)		
occurrences (all)	58		
Gastrointestinal disorders			

Diarrhoea subjects affected / exposed occurrences (all)	77 / 1732 (4.45%) 90		
Nausea subjects affected / exposed occurrences (all)	24 / 1732 (1.39%) 28		
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all)	22 / 1732 (1.27%) 25		
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	26 / 1732 (1.50%) 57		
Musculoskeletal and connective tissue disorders Athralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all) Musculoskeletal pain subjects affected / exposed occurrences (all)	55 / 1732 (3.18%) 70 45 / 1732 (2.60%) 55 44 / 1732 (2.54%) 51 20 / 1732 (1.15%) 21		
Infections and infestations Upper Respiratory Tract Infection subjects affected / exposed occurrences (all) Nasalpharyngitis subjects affected / exposed occurrences (all) Bronchitis	100 / 1732 (5.77%) 127 53 / 1732 (3.06%) 64		

subjects affected / exposed	29 / 1732 (1.67%)		
occurrences (all)	34		
Influenza			
subjects affected / exposed	26 / 1732 (1.50%)		
occurrences (all)	38		
Urinary tract infection			
subjects affected / exposed	19 / 1732 (1.10%)		
occurrences (all)	26		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 June 2011	The primary purpose of this amendment was to provide consistency with the proposed Phase 3 and to address the Institutional Review Board questions regarding genetic testing.
21 June 2011	The purposes of this amendment was to increase the global scale of this study to encompass a greater diversity of patients in multiple countries and regions; To clarify minimum dose of allopurinol allowed; To examine additional patient reported outcomes to further our understanding of patient knowledge and experience of gout before, during and after treatment.
25 July 2011	This amendment was implemented at a limited (but large) number of investigational sites in the United States and Canada in order generate preliminary data intended to potentially guide future hypothesis-testing in subsequent gout studies.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported