Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, and Efficacy of MK-0822 in the Treatment of Postmenopausal Women With Osteoporosis; A 12-Month Extension to: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, and Efficacy of MK-0822 (Cathepsin-K Inhibitor) in the Treatment of Postmenopausal Women With Osteoporosis; A 24-Month Extension to: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, and Efficacy of Odanacatib (MK-0822) in the Treatment of Postmenopausal Women With Osteoporosis; and A 5-Year Open-Label Extension to: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, and Efficacy of Odanacatib (MK-0822) in the Treatment of Postmenopausal Women With Osteoporosis

Summary

EudraCT number	2005-001511-22
Trial protocol	SE DK GB
Global end of trial date	20 January 2016

Results information

Result version number	v2 (current)
This version publication date	18 July 2018
First version publication date	04 February 2017
Version creation reason	• Correction of full data set updating to be consistent with ClinicalTrials.gov record

Trial information

Trial identification

Sponsor protocol code	0822-004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00112437
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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	20 January 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 January 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the study were: 1) To estimate the change from baseline (randomization in Protocol 004-02) in bone mineral density (BMD) at the lumbar spine at Years 8 and 10 with 50 mg of odanacatib once weekly in postmenopausal osteoporotic women previously treated for up to 5 years with odanacatib once weekly (in Protocols 004-02, 004-11, and 004-22); and 2) To assess the safety of treatment with odanacatib 50 mg once weekly for up to 10 years.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 June 2005
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 15
Country: Number of subjects enrolled	Austria: 24
Country: Number of subjects enrolled	Chile: 15
Country: Number of subjects enrolled	Colombia: 22
Country: Number of subjects enrolled	Denmark: 24
Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	Mexico: 19
Country: Number of subjects enrolled	New Zealand: 28
Country: Number of subjects enrolled	Norway: 30

Country: Number of subjects enrolled	Peru: 20
Country: Number of subjects enrolled	Sweden: 20
Country: Number of subjects enrolled	Switzerland: 17
Country: Number of subjects enrolled	United Kingdom: 15
Country: Number of subjects enrolled	United States: 132
Worldwide total number of subjects	399
EEA total number of subjects	131

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)	223
From 65 to 84 years	174
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Approximately 375 participants were recruited from June 2005 to December 2005. Investigators used one or more of the following recruitment methods: Investigator Patient/Subject Database or Medical Records, Investigator's Local Recruitment/Advertising, Other Health Professional and, Physician Referral (Primary/Specialist/Family Doctor).

Pre-assignment

Screening details:

Participants entered screening followed by a 3-week placebo run-in. All took vitamin D3, 5600 IU once weekly, those with average daily calcium intakes <1000 mg took calcium 500 mg/day as calcium carbonate. Participants were excluded from active treatment based on predetermined exclusion criteria (BMD and laboratory results).

Period 1

Period 1 title	YEAR 1 (12-Month Base Study)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo-Base

Arm description:

One placebo tablet once a week

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

Dosage and administration details:

One placebo tablet once a week

Arm title	Odanacatib 3 mg-Base

Arm description:

One odanacatib 3 mg tablet once a week

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 3 mg tablet once a week

Arm title	Odanacatib 10 mg-Base

Arm description:

One odanacatib 10 mg tablet once a week

Arm type	Experimental

Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 10 mg tablet once a week

Arm title	Odanacatib 25 mg-Base

Arm description:

One odanacatib 25 mg tablet once a week

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 25 mg tablet once a week

Arm title	Odanacatib 50 mg-Base

Arm description:

One odanacatib 50 mg tablet once a week

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Number of subjects in period 1	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base
Started	83	82	77
Completed	68	64	65
Not completed	15	18	12
Consent withdrawn by subject	5	5	2
Adverse event, non-fatal	9	10	6
DXA was lower by more than 8%	-	-	-
Lost to follow-up	-	1	-
Moved	-	1	1
patient was unsure that they needed drug	-	-	-
Protocol deviation	1	-	3
Lack of efficacy	-	1	-

Number of subjects in period 1	Odanacatib 25 mg-Base	Odanacatib 50 mg-Base

Started	79	78
Completed	71	66
Not completed	8	12
Consent withdrawn by subject	1	7
Adverse event, non-fatal	4	3
DXA was lower by more than 8%	-	1
Lost to follow-up	-	-
Moved	-	-
patient was unsure that they needed drug	2	-
Protocol deviation	1	1
Lack of efficacy	-	-

Period 2

Period 2 title	YEAR 2 (12-Month Extension)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo-Ext 1

Arm description:

One placebo tablet once a week

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

Dosage and administration details:

One placebo tablet once a week

Arm title	Odanacatib 3 mg-Ext 1

Arm description:

One odanacatib 3 mg tablet once a week

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 3 mg tablet once a week

Arm title	Odanacatib 10 mg-Ext 1

Arm description:	
One odanacatib 10 mg tablet once a week	
Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
One 10 mg tablet once a week	
Arm title	Odanacatib 25 mg-Ext 1
Arm description:	
One odanacatib 25 mg tablet once a week	
Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
One 25 mg tablet once a week	
Arm title	Odanacatib 50 mg-Ext 1
Arm description:	
One odanacatib 50 mg tablet once a week	
Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
One 50 mg tablet once a week	

Number of subjects in period 2[1]	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1
Started	63	62	63
Completed	60	53	55
Not completed	3	9	8
Consent withdrawn by subject	1	1	2
Adverse event, non-fatal	1	2	6
Patient stopped taking medication	-	-	-
patient was out of windows	-	-	-
Lost to follow-up	-	-	-
Moved	-	-	-
Lack of efficacy	1	6	-

Protocol deviation	-	-	-

Number of subjects in period 2[1]	Odanacatib 25 mg-Ext 1	Odanacatib 50 mg-Ext 1
Started	69	63
Completed	62	50
Not completed	7	13
Consent withdrawn by subject	4	1
Adverse event, non-fatal	1	7
Patient stopped taking medication	-	1
patient was out of windows	-	1
Lost to follow-up	1	-
Moved	-	1
Lack of efficacy	-	2
Protocol deviation	1	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all participants who completed the preceding period entered this extension.

Period 3

Period 3 title	YEAR 3 (12-Month Extension)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo/Placebo-Ext 2

Arm description:

During this 12-month extension (Year 3), participants in this treatment group took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one placebo tablet once a week for 2 years.

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

Dosage and administration details:

One placebo tablet once a week

Arm title	Placebo/Odanacatib 50 mg-Ext 2

Arm description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one placebo tablet once a week for 2 years.

Arm type	Experimental

Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Arm title	Odanacatib 3 mg/Placebo-Ext 2

Arm description:

During this 12-month extension (Year 3), participants took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one 3 mg tablet of odanacatib once a week for 2 years.

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

Dosage and administration details:

One placebo tablet once a week

Arm title	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2

Arm description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one 3 mg tablet of odanacatib once a week for 2 years.

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Arm title	Odanacatib 10 mg/Placebo-Ext 2

Arm description:

During this 12-month extension (Year 3), participants took one placebo tablet once a week. Before entering this extension, participants had taken one 10 mg tablet of odanacatib once a week for 2 years.

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

Dosage and administration details:

One placebo tablet once a week

Arm title	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2

Arm description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group took one 10 mg tablet of odanacatib once a week for 2 years.

Arm type	Experimental

Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Arm title	Odanacatib 25 mg/Placebo-Ext 2

Arm description:

During this 12-month extension (Year 3), participants in this treatment group took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one 25 mg tablet of odanacatib once a week for 2 years.

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

Dosage and administration details:

One placebo tablet once a week

Arm title	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2

Arm description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one 25 mg tablet of odanacatib once a week for 2 years.

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Arm title	Odanacatib 50 mg/Placebo-Ext 2

Arm description:

During this 12-month extension (Year 3), participants in this treatment group took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one 50 mg tablet of odanacatib once a week for 2 years.

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

Dosage and administration details:

One placebo tablet once a week

Arm title	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2

Arm description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one 50 mg tablet of odanacatib once a week for 2 years.

Arm type	Experimental

Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Number of subjects in period 3[2]	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2
Started	19	22	18
Completed	17	17	18
Not completed	2	5	0
Consent withdrawn by subject	-	3	-
Adverse event, non-fatal	1	-	-
Lost to follow-up	-	-	-
cortisone therapy, upcoming surgery	1	1	-
Lack of efficacy	-	1	-
Protocol deviation	-	-	-

Number of subjects in period 3[2]	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2
Started	17	18	17
Completed	16	17	13
Not completed	1	1	4
Consent withdrawn by subject	-	1	-
Adverse event, non-fatal	-	-	1
Lost to follow-up	-	-	1
cortisone therapy, upcoming surgery	-	-	-
Lack of efficacy	1	-	1
Protocol deviation	-	-	1

Number of subjects in period 3[2]	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2	Odanacatib 50 mg/Placebo-Ext 2
Started	19	21	18
Completed	16	20	16
Not completed	3	1	2
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	3	1	-
Lost to follow-up	-	-	-
cortisone therapy, upcoming surgery	-	-	-

Lack of efficacy	-	-	2
Protocol deviation	-	-	-

Number of subjects in period 3[2]	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Started	20
Completed	19
Not completed	1
Consent withdrawn by subject	-
Adverse event, non-fatal	1
Lost to follow-up	-
cortisone therapy, upcoming surgery	-
Lack of efficacy	-
Protocol deviation	-

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all participants who completed the preceding period entered this extension.

Period 4

Period 4 title	YEARS 4-5 (24-Month Extension)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo once weekly

Arm description:

One placebo tablet once a week

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

Dosage and administration details:

One placebo tablet once a week

Arm title	Odanacatib 50 mg once weekly

Arm description:

One odanacatib 50 mg tablet once a week

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Number of subjects in period 4[3]	Placebo once weekly	Odanacatib 50 mg once weekly
Started	41	100
Completed	37	92
Not completed	4	8
Participant moved	-	1
Consent withdrawn by subject	1	2
Adverse event, non-fatal	-	4
Participant discontinued for other reason	1	-
Lack of efficacy	2	1

Notes:

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

Justification: Not all participants who completed the preceding period entered this extension.

Period 5

Period 5 title	YEARS 6-10 (60-Month Extension)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A: Odanacatib 50 mg once weekly

Arm description:

Group A consists of a combination of participants who were treated with odanacatib 25 mg for 2 years, then odanacatib 50 mg for 8 years; and participants who were treated with odanacatib 50 mg for 10 years.

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Arm title	Group B: Odanacatib 50 mg once weekly

Arm description:

Group B consists of a combination participants who were treated with placebo for 2 years, then

odanacatib 50 mg for 8 years; participants who were treated with odanacatib 3 mg for 2 years, then odanacatib 50 mg for 8 years; and participants who were treated with odanacatib 10 mg for 2 years, then odanacatib 50 mg for 8 years.

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Arm title	Group C: Odanacatib 50 mg once weekly

Arm description:

Group C consists of a combination of participants who were treated with placebo for 3 years, then odanacatib 50 mg for 7 years; and participants who were treated with odanacatib 3 mg for 2 years, then placebo for 1 year, then odanacatib 50 mg for 7 years.

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Arm title	Group D: Odanacatib 50 mg once weekly

Arm description:

Group D consists of a combination of participants who were treated with odanacatib 10 mg for 2 years, then placebo for 3 years, then odanacatib 50 mg for 5 years; participents who were treated with odanacatib 25 mg for 5 years, then placebo for 3 years, then odanacatib 50 mg for 5 years; and participants who were treated with odanacatib 50 mg for 2 years, then placebo for 3 years, then odanacatib 50 mg for 5 years.

Arm type	Experimental
Investigational medicinal product name	Odanacatib
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 50 mg tablet once a week

Number of subjects in period 5[4]	Group A: Odanacatib 50 mg once weekly	Group B: Odanacatib 50 mg once weekly	Group C: Odanacatib 50 mg once weekly
Started	28	34	23
Completed	23	22	22
Not completed	5	12	1
Physician decision	-	2	-
Adverse event, non-fatal	1	2	-
Death	-	2	-

Other	-	-	1
Lost to follow-up	-	-	-
Withdrawal by subject	4	6	-

Number of subjects in period 5[4]	Group D: Odanacatib 50 mg once weekly
Started	32
Completed	27
Not completed	5
Physician decision	-
Adverse event, non-fatal	1
Death	-
Other	-
Lost to follow-up	1
Withdrawal by subject	3

Notes:

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

Justification: Not all participants who completed the preceding period entered this extension.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo-Base
Reporting group description:	
One placebo tablet once a week	
Reporting group title	Odanacatib 3 mg-Base
Reporting group description:	
One odanacatib 3 mg tablet once a week	
Reporting group title	Odanacatib 10 mg-Base
Reporting group description:	
One odanacatib 10 mg tablet once a week	
Reporting group title	Odanacatib 25 mg-Base
Reporting group description:	
One odanacatib 25 mg tablet once a week	
Reporting group title	Odanacatib 50 mg-Base
Reporting group description:	
One odanacatib 50 mg tablet once a week	

Reporting group values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base
Number of subjects	83	82	77
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	65.9	63.1	64.5
standard deviation	± 7.8	± 7.3	± 8
Gender categorical			
Units: Subjects			
Female	83	82	77
Male	0	0	0

Reporting group values	Odanacatib 25 mg-Base	Odanacatib 50 mg-Base	Total
Number of subjects	79	78	399
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	62.9	64.5	
standard deviation	± 7.4	± 8.1	-
Gender categorical			
Units: Subjects			
Female	79	78	399
Male	0	0	0

End points

End points reporting groups

Reporting group title	Placebo-Base
Reporting group description:	
One placebo tablet once a week	
Reporting group title	Odanacatib 3 mg-Base
Reporting group description:	
One odanacatib 3 mg tablet once a week	
Reporting group title	Odanacatib 10 mg-Base
Reporting group description:	
One odanacatib 10 mg tablet once a week	
Reporting group title	Odanacatib 25 mg-Base
Reporting group description:	
One odanacatib 25 mg tablet once a week	
Reporting group title	Odanacatib 50 mg-Base
Reporting group description:	
One odanacatib 50 mg tablet once a week	
Reporting group title	Placebo-Ext 1
Reporting group description:	
One placebo tablet once a week	
Reporting group title	Odanacatib 3 mg-Ext 1
Reporting group description:	
One odanacatib 3 mg tablet once a week	
Reporting group title	Odanacatib 10 mg-Ext 1
Reporting group description:	
One odanacatib 10 mg tablet once a week	
Reporting group title	Odanacatib 25 mg-Ext 1
Reporting group description:	
One odanacatib 25 mg tablet once a week	
Reporting group title	Odanacatib 50 mg-Ext 1
Reporting group description:	
One odanacatib 50 mg tablet once a week	
Reporting group title	Placebo/Placebo-Ext 2
Reporting group description:	
During this 12-month extension (Year 3), participants in this treatment group took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one placebo tablet once a week for 2 years.	
Reporting group title	Placebo/Odanacatib 50 mg-Ext 2
Reporting group description:	
During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one placebo tablet once a week for 2 years.	
Reporting group title	Odanacatib 3 mg/Placebo-Ext 2
Reporting group description:	
During this 12-month extension (Year 3), participants took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one 3 mg tablet of odanacatib once a week for 2 years.	
Reporting group title	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Reporting group description:	
During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one 3 mg tablet of odanacatib once a week for 2 years.	

Reporting group title	Odanacatib 10 mg/Placebo-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one placebo tablet once a week. Before entering this extension, participants had taken one 10 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group took one 10 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Odanacatib 25 mg/Placebo-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants in this treatment group took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one 25 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one 25 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Odanacatib 50 mg/Placebo-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants in this treatment group took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one 50 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one 50 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Placebo once weekly

Reporting group description:

One placebo tablet once a week

Reporting group title	Odanacatib 50 mg once weekly

Reporting group description:

One odanacatib 50 mg tablet once a week

Reporting group title	Group A: Odanacatib 50 mg once weekly

Reporting group description:

Group A consists of a combination of participants who were treated with odanacatib 25 mg for 2 years, then odanacatib 50 mg for 8 years; and participants who were treated with odanacatib 50 mg for 10 years.

Reporting group title	Group B: Odanacatib 50 mg once weekly

Reporting group description:

Group B consists of a combination participants who were treated with placebo for 2 years, then odanacatib 50 mg for 8 years; participants who were treated with odanacatib 3 mg for 2 years, then odanacatib 50 mg for 8 years; and participants who were treated with odanacatib 10 mg for 2 years, then odanacatib 50 mg for 8 years.

Reporting group title	Group C: Odanacatib 50 mg once weekly

Reporting group description:

Group C consists of a combination of participants who were treated with placebo for 3 years, then odanacatib 50 mg for 7 years; and participants who were treated with odanacatib 3 mg for 2 years, then placebo for 1 year, then odanacatib 50 mg for 7 years.

Reporting group title	Group D: Odanacatib 50 mg once weekly

Reporting group description:

Group D consists of a combination of participants who were treated with odanacatib 10 mg for 2 years, then placebo for 3 years, then odanacatib 50 mg for 5 years; participents who were treated with odanacatib 25 mg for 5 years, then placebo for 3 years, then odanacatib 50 mg for 5 years; and participants who were treated with odanacatib 50 mg for 2 years, then placebo for 3 years, then odanacatib 50 mg for 5 years.

Primary: Percentage Change From Baseline in Lumbar Spine Bone Mineral Density (BMD) at 12 Months

End point title	Percentage Change From Baseline in Lumbar Spine Bone Mineral Density (BMD) at 12 Months

End point description:

Percentage change in lumbar spine BMD (relative to baseline) at 12 months.

Analysis at Month 12 used Full-Analysis-Set (FAS) Population of patients who took at least one dose of study medication and had necessary follow-up information, in their randomization treatment group, with last observation data carried forward. Seven patients had a baseline value, but no value at Month 12 for lumbar spine BMD.

End point type	Primary

End point timeframe:

Baseline and 12 months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	79	77	78
Units: Percent Change				
least squares mean (confidence interval 95%)	-0.13 (-0.8 to 0.54)	-0.62 (-1.3 to 0.05)	1.5 (0.82 to 2.19)	2.65 (1.97 to 3.33)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: Percent Change				
least squares mean (confidence interval 95%)	3.37 (2.68 to 4.05)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The primary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Lumbar Spine BMD compared to placebo over 12 months. The primary hypothesis states that odanacatib will increase Lumbar Spine BMD compared to placebo over 12 months.

Comparison groups	Odanacatib 50 mg-Base v Placebo-Base

Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [1]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	3.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.54
upper limit	4.45

Notes:

[1] - Significance for the primary endpoint was achieved through stepdown trend-test, the highest dose group was removed and the test was repeated until lack of significance was observed.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The primary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Lumbar Spine BMD compared to placebo over 12 months. The primary hypothesis states that odanacatib will increase Lumbar Spine BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [2]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.82
upper limit	3.73

Notes:

[2] - Significance for the primary endpoint was achieved through stepdown trend-test, the highest dose group was removed and the test was repeated until lack of significance was observed.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The primary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Lumbar Spine BMD compared to placebo over 12 months. The primary hypothesis states that odanacatib will increase Lumbar Spine BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.003 [3]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	1.63

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	2.59

Notes:

[3] - Significance for the primary endpoint was achieved through stepdown trend-test, the highest dose group was removed and the test was repeated until lack of significance was observed.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The primary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Lumbar Spine BMD compared to placebo over 12 months. The primary hypothesis states that odanacatib will increase Lumbar Spine BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.343 [4]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.44
upper limit	0.46

Notes:

[4] - Significance for the primary endpoint was achieved through stepdown trend-test, the highest dose group was removed and the test was repeated until lack of significance was observed.

Primary: Percentage Change From Baseline in Lumbar Spine BMD at 24 Months

End point title	Percentage Change From Baseline in Lumbar Spine BMD at 24 Months

End point description:

Percentage change in lumbar spine BMD (relative to baseline) at 24 months.

Analysis on lumbar spine BMD (g/cm2) at Month 24 used the FAS Population with Last Observation Carried Forward from Month 18 to 24. No data were carried forward from the core to the extension period. Only patients who took at least one dose of extension medication were included. 17 patients were excluded from FAS.

End point type	Primary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	58	60	65
Units: Percent Change				
least squares mean (confidence interval 95%)	-0.19 (-1.13 to 0.75)	-1.03 (-2 to -0.07)	3.2 (2.25 to 4.15)	4.26 (3.35 to 5.18)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: Percent Change				
least squares mean (confidence interval 95%)	5.48 (4.52 to 6.44)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The primary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Lumbar Spine BMD compared to placebo over 24 months. The primary hypothesis states that odanacatib will increase Lumbar Spine BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [5]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	5.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.32
upper limit	7.02

Notes:

[5] - Significance for the primary endpoint was achieved through stepdown trend-test, the highest dose group was removed and the test was repeated until lack of significance was observed.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The primary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Lumbar Spine BMD compared to placebo over 24 months. The primary hypothesis states that odanacatib will increase Lumbar Spine BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1

Number of subjects included in analysis	127
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [6]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	4.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.15
upper limit	5.76

Notes:

[6] - Significance for the primary endpoint was achieved through stepdown trend-test, the highest dose group was removed and the test was repeated until lack of significance was observed.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The primary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Lumbar Spine BMD compared to placebo over 24 months. The primary hypothesis states that odanacatib will increase Lumbar Spine BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [7]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	3.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.06
upper limit	4.73

Notes:

[7] - Significance for the primary endpoint was achieved through stepdown trend-test, the highest dose group was removed and the test was repeated until lack of significance was observed.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The primary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Lumbar Spine BMD compared to placebo over 24 months. The primary hypothesis states that odanacatib will increase Lumbar Spine BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.218 [8]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.84

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.19
upper limit	0.51

Notes:

[8] - Significance for the primary endpoint was achieved through stepdown trend-test, the highest dose group was removed and the test was repeated until lack of significance was observed.

Primary: Percentage Change From Baseline in Lumbar Spine BMD at 36 Months

End point title	Percentage Change From Baseline in Lumbar Spine BMD at 36 Months

End point description:

Percentage change in lumbar spine BMD (relative to baseline) at 36 months.

This analysis was performed at Month 36 using the Per Protocol (PP) Population, which included participants who took at least one dose of extension study medication and had the necessary follow-up information. Missing values were not imputed. No data were carried forward from Month 30 to 36.

End point type	Primary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	16	17	13
Units: Percent Change				
least squares mean (confidence interval 95%)	0.42 (-1.89 to 2.73)	2.95 (0.79 to 5.11)	-1.57 (-3.67 to 0.54)	4.41 (2.01 to 6.82)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	12	18
Units: Percent Change				
least squares mean (confidence interval 95%)	2.03 (-0.47 to 4.53)	6.11 (3.37 to 8.85)	0.32 (-2.18 to 2.82)	7.45 (5.41 to 9.48)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	17		
Units: Percent Change				
least squares mean (confidence interval	1.39 (-0.84 to	7.85 (5.74 to		

95%)	3.63)	9.95)

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

In postmenopausal women with osteoporosis assess the time course of resolution of effect on Lumbar Spine BMD during the 12 month extension following 24 months of treatment with odanacatib once weekly. The primary objective was to assess the resolution of effect, on lumbar spine BMD, for the patients who received odanacatib 50 mg for 3 years compared to those who received odanacatib 50 mg in the 2 year base period and switched to placebo for the 3rd year extension.

Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	6.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.38
upper limit	9.53

Primary: Percentage Change From Baseline in Lumbar Spine BMD at 60 Months

End point title	Percentage Change From Baseline in Lumbar Spine BMD at 60 Months[9]

End point description:

Percentage change from baseline in lumbar spine BMD at 60 months.

This analysis was based on the Full-Analysis Set (FAS) population, last observation carried forward. All patients who took at least one dose of base study medication were included in the base study time points, while for the extension study time points only patients who took at least one dose of extension medication were included. Missing values were imputed using the last observation-carried-forward principle for the FAS approach.

End point type	Primary

End point timeframe:

Baseline and 60 months

Notes:

[9] - 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 between-group statistical analyses were performed for the endpoint: Percentage Change From Baseline in Lumbar Spine BMD at 60 Months

End point values	Placebo once weekly	Odanacatib 50 mg once weekly		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	13		
Units: Percent change				
arithmetic mean (confidence interval 95%)	-0.41 (-3.1 to 2.28)	11.88 (7.23 to 16.54)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage Change From Baseline in Lumbar Spine BMD at 120 Months

End point title	Percentage Change From Baseline in Lumbar Spine BMD at 120 Months[10]

End point description:

Percentage change from baseline in lumbar spine BMD at 120 Months.

This analysis was based on the FAS population, which included all randomized participants who took at least 1 dose of extension study drug and had the necessary extension data available for this endpoint. Missing data were not imputed.

End point type	Primary

End point timeframe:

Baseline and 120 months

Notes:

[10] - 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 between-group statistical analyses were performed for the endpoint: Percentage Change From Baseline in Lumbar Spine BMD at 120
Months.

End point values	Group A: Odanacatib 50 mg once weekly	Group B: Odanacatib 50 mg once weekly	Group C: Odanacatib 50 mg once weekly	Group D: Odanacatib 50 mg once weekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	16	17	21
Units: Percent change				
arithmetic mean (confidence interval 95%)	16.92 (12.28 to 21.55)	14.56 (11.1 to 18.02)	17.18 (11.48 to 22.88)	7.71 (4.46 to 10.95)

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Who Experienced At Least One Adverse Event (AE) During Treatment Years 6-10 (60 Months)

End point title	Number of Participants Who Experienced At Least One Adverse Event (AE) During Treatment Years 6-10 (60 Months)[11]

End point description:

Number of participants who experienced at least one adverse event (AE) during treatment years 6-10

(60 months).

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study drug, whether or not it is considered related to the study drug.

This endpoint was based on the All Participants As Treated (APaT) population, consisting of all participants who received at least 1 administration of the trial drug during treatment years 6-10.

End point type	Primary

End point timeframe:

Years 6-10 (up to 60 months, up to 14 days after the last dose of study drug)

Notes:

[11] - 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 between-group statistical analyses were performed for the endpoint: Number of Participants Who Experienced At Least One Adverse Event (AE) During Treatment Years 6-10 (60 Months).

End point values	Group A: Odanacatib 50 mg once weekly	Group B: Odanacatib 50 mg once weekly	Group C: Odanacatib 50 mg once weekly	Group D: Odanacatib 50 mg once weekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	34	23	32
Units: Participants	27	34	23	32

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Who Discontinued Study Drug Due to an AE During Treatment Years 6-10 (60 Months)

End point title	Number of Participants Who Discontinued Study Drug Due to an AE During Treatment Years 6-10 (60 Months)[12]

End point description:

Number of participants who discontinued study treatment drug due to an AE during treatment years 6-10 (60 months)

An AE is defined as any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study drug, whether or not it is considered related to the study drug. This endpoint was based on the APaT population, consisting of all participants who received at least 1 administration of the trial drug during treatment years 6-10.

End point type	Primary

End point timeframe:

Years 6-10 (up to 60 months)

Notes:

[12] - 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 between-group statistical analyses were performed for the endpoint: Number of Participants Who Discontinued Study Drug Due to an AE During Treatment Years 6-10 (60 Months)

End point values	Group A: Odanacatib 50 mg once weekly	Group B: Odanacatib 50 mg once weekly	Group C: Odanacatib 50 mg once weekly	Group D: Odanacatib 50 mg once weekly
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	34	23	32
Units: Participants	1	2	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change From Baseline in Total Hip BMD at 12 Months

End point title	Percentage Change From Baseline in Total Hip BMD at 12 Months

End point description:

Percentage change in total hip BMD (relative to baseline) at 12 months.

This analysis was performed at Month 12 using FAS population with Last Observation Carried Forward.

End point type	Secondary

End point timeframe:

Baseline and 12 months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	79	77	78
Units: Percent Change				
least squares mean (confidence interval 95%)	-0.61 (-1.22 to -0.01)	-1.36 (-1.97 to -0.75)	1.05 (0.44 to 1.67)	1.45 (0.84 to 2.07)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: Percent Change				
least squares mean (confidence interval 95%)	1.87 (1.25 to 2.49)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg

weekly, and 50 mg weekly on Total Hip BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase Total Hip BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [13]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.62
upper limit	3.35

Notes:

[13] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through a stepdown trend-test approach. Multiplicity for multiple endpoints was handled by a Hochberg procedure

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Hip BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase Total Hip BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [14]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	2.93

Notes:

[14] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through a stepdown trend-test approach. Multiplicity for multiple endpoints was handled by a Hochberg procedure

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Hip BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase Total Hip BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base

Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [15]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	1.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	2.53

Notes:

[15] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through a stepdown trend-test approach. Multiplicity for multiple endpoints was handled by a Hochberg procedure

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Hip BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase Total Hip BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.135 [16]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.61
upper limit	0.11

Notes:

[16] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through a stepdown trend-test approach. Multiplicity for multiple endpoints was handled by a Hochberg procedure

Secondary: Percentage Change From Baseline in Femoral Neck BMD at 12 Months

End point title	Percentage Change From Baseline in Femoral Neck BMD at 12 Months

End point description:

Percentage change in femoral neck BMD (relative to baseline) at 12 months.

This analysis was performed at Month 12 using FAS population with Last Observation Carried Forward.

End point type	Secondary

End point timeframe:

Baseline and 12 months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	79	77	78
Units: Percentage change				
least squares mean (confidence interval 95%)	-0.13 (-0.79 to 0.54)	-0.32 (-0.99 to 0.35)	0.74 (0.05 to 1.42)	1.76 (1.08 to 2.44)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: Percentage change				
least squares mean (confidence interval 95%)	2.53 (1.85 to 3.21)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on femoral neck BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase femoral neck BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	
P-value	≤ 0.001 [17]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.71
upper limit	3.61

Notes:

[17] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on femoral neck BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase femoral neck BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base

Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [18]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	2.84

Notes:

[18] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on femoral neck BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase femoral neck BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.095 [19]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	1.82

Notes:

[19] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on femoral neck BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase femoral neck BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.19

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.14
upper limit	0.75

Secondary: Percentage Change From Baseline in Trochanter BMD at 12 Months

End point title	Percentage Change From Baseline in Trochanter BMD at 12 Months

End point description:

Percentage change in trochanter BMD (relative to baseline) at 12 months.

This analysis was performed at Month 12 using FAS population with Last Observation Carried Forward.

End point type	Secondary

End point timeframe:

Baseline and 12 Months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	79	77	78
Units: Percentage change				
least squares mean (confidence interval 95%)	-0.73 (-1.64 to 0.18)	-1.02 (-1.94 to -0.1)	1.65 (0.72 to 2.58)	1.91 (0.99 to 2.84)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: Percentage change				
least squares mean (confidence interval 95%)	2.21 (1.28 to 3.14)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on trochanter BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase trochanter BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base

Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [20]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.64
upper limit	4.24

Notes:

[20] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on trochanter BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase trochanter BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [21]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.35
upper limit	3.94

Notes:

[21] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on trochanter BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase trochanter BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [22]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.38

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.08
upper limit	3.69

Notes:

[22] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on trochanter BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase trochanter BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.731 [23]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.58
upper limit	1

Notes:

[23] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Secondary: Percentage Change From Baseline in Total Body BMD at 12 Months

End point title	Percentage Change From Baseline in Total Body BMD at 12 Months

End point description:

Percentage change in total body BMD (relative to baseline) at 12 months.

This analysis was performed at Month 12 using the FAS population with Last Observation Carried Forward.

End point type	Secondary

End point timeframe:

Baseline and 12 Months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	72	71	70	75
Units: Percentage change				
least squares mean (confidence interval 95%)	-0.42 (-1.16 to 0.32)	-1.89 (-2.64 to -1.14)	-1.06 (-1.81 to -0.3)	-0.51 (-1.23 to 0.22)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Percentage change				
least squares mean (confidence interval 95%)	-0.13 (-0.89 to 0.62)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on total body BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase total body BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.112 [24]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.77
upper limit	1.35

Notes:

[24] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on total body BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase total body BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.09

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.13
upper limit	0.95

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on total body BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase total body BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	142
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.69
upper limit	0.42

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on total body BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase total body BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.53
upper limit	-0.42

Secondary: Percentage Change From Baseline in Distal Forearm BMD at 12 Months

End point title	Percentage Change From Baseline in Distal Forearm BMD at 12 Months

End point description:

Percentage change in distal forearm BMD (relative to baseline) at 12 months.

This analysis was performed at Month 12 using the FAS population with Last Observation Carried Forward.

End point type	Secondary

End point timeframe:

Baseline and 12 Months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	81	79	77	78
Units: Percentage change				
least squares mean (confidence interval 95%)	-1.27 (-1.98 to -0.57)	-2.55 (-3.26 to -1.83)	-1 (-1.73 to -0.28)	-0.17 (-0.89 to 0.55)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	77			
Units: Percentage change				
least squares mean (confidence interval 95%)	-0.04 (-0.77 to 0.68)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on distal forearm BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase distal forearm BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [25]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	2.24

Notes:

[25] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on distal forearm BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase distal forearm BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.005 [26]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.09
upper limit	2.11

Notes:

[26] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on distal forearm BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase distal forearm BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	158
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.63 [27]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.74
upper limit	1.29

Notes:

[27] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg

weekly, and 50 mg weekly on distal forearm BMD compared to placebo over 12 months. The secondary hypothesis states that odanacatib will increase distal forearm BMD compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	160
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.28
upper limit	-0.27

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary N-telopeptides of Type I Collagen [u-NTx]) at 12 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary N-telopeptides of Type I Collagen [u-NTx]) at 12 Months

End point description:

Back-transformation (geometric mean) of the least squares (LS) mean of the log-values percentage change from baseline, in biochemical marker of bone turnover (u-NTx) at 12 months.

This analysis was geometric mean percent change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 12 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP population approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 12 Months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	57	56	63
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-2.37 (-14.78 to 11.85)	8.8 (-5.5 to 25.27)	-34.21 (-42.94 to -24.15)	-48.29 (-54.8 to -40.84)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	56			
Units: Geometric LS Mean percent change				

least squares mean (confidence interval 95%)	-60.23 (-65.51 to -54.13)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-NTx) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-NTx) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [28]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-57.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-72.33
upper limit	-43.38

Notes:

[28] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-NTx) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-NTx) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [29]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-45.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-60.93
upper limit	-30.91

Notes:

[29] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-NTx) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-NTx) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [30]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-31.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.11
upper limit	-15.58

Notes:

[30] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-NTx) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-NTx) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.249 [31]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	11.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.94
upper limit	43.24

Notes:

[31] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum C-telopeptides of Type 1 Collagen [s-CTx]) at 12 Months

End point title	Percentage Change From Baseline in Biochemical Marker of

	Bone Turnover (Serum C-telopeptides of Type 1 Collagen [s-CTx]) at 12 Months

End point description:

Back-transformation (geometric mean) of the least squares (LS) mean of the log-values percentage change from baseline in biochemical marker of bone turnover (s-CTx) at 12 Months.

This analysis was geometric mean percent change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 12 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP population approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 12 Months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	57	56	62
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-0.58 (-16.79 to 18.78)	19.12 (-0.94 to 43.24)	-22.24 (-35.45 to -6.32)	-36.15 (-46.54 to -23.75)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-56.91 (-64.31 to -47.99)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (s-CTx) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (s-CTx) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [32]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-56.33

Confidence interval	
level	95 %
sides	2-sided
lower limit	-75.86
upper limit	-36.81

Notes:

[32] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (s-CTx) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (s-CTx) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [33]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-35.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-56.63
upper limit	-14.51

Notes:

[33] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (s-CTx) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (s-CTx) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.08 [34]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-21.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.54
upper limit	1.23

Notes:

[34] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (s-CTx) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (s-CTx) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	19.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.48
upper limit	47.88

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary Total Deoxypyridinolines [u-DPyr]) at 12 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary Total Deoxypyridinolines [u-DPyr]) at 12 Months

End point description:

Back-transformation (geometric mean) of the least squares mean of the log-values Percentage change in niochemical marker of bone turnover (u-DPyr) (relative to baseline) at 12 months.

This analysis was geometric mean percent change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 12 using a PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP population approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 12 months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	57	55	63
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-7.25 (-19.73 to 7.18)	20.91 (4.33 to 40.12)	-8.58 (-21.33 to 6.24)	-8.5 (-20.52 to 5.33)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-25.52 (-35.93 to -13.43)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-DPyr) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-DPyr) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.004 [35]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-18.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.82
upper limit	-0.74

Notes:

[35] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-DPyr) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-DPyr) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.344 [36]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-1.26

Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.9
upper limit	17.39

Notes:

[36] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-DPyr) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-DPyr) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.55
upper limit	17.89

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-DPyr) compared to placebo over 12 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-DPyr) over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	28.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.84
upper limit	50.46

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone

Turnover (Serum Bone-specific Alkaline Phosphatase [s-BSAP]) at 12 Months	
End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum Bone-specific Alkaline Phosphatase [s-BSAP]) at 12 Months

End point description:

Back-transformation (geometric mean) of the least squares mean of the log-values percentage change from baseline, in biochemical marker of bone turnover (s-BSAP), at 12 months.

This analysis was geometric mean percent change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 12 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP population approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 12 months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	58	57	64
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-2.77 (-10.39 to 5.49)	42.08 (30.64 to 54.52)	8.95 (0.1 to 18.6)	2.66 (-5.25 to 11.24)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-18.35 (-24.93 to -11.18)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-BSAP) compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [37]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-15.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.11
upper limit	-5.04

Notes:

[37] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-BSAP) compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.645 [38]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	5.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.02
upper limit	16.89

Notes:

[38] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-BSAP) compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	11.73

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.47
upper limit	23.92

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-BSAP) compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	44.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.55
upper limit	59.16

Secondary: Percentage Change in Biochemical Marker of Bone Turnover (Serum N-terminal Propeptide of Type 1 Collagen [s-P1NP]) at 12 Months

End point title	Percentage Change in Biochemical Marker of Bone Turnover (Serum N-terminal Propeptide of Type 1 Collagen [s-P1NP]) at 12 Months

End point description:

Back-transformation (geometric mean) of the least squares mean of the log-values percentage change in biochemical marker of bone turnover (s-P1NP) (relative to baseline) at 12 months.

This analysis was geometric mean percent change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 12 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP population approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 12 months

End point values	Placebo-Base	Odanacatib 3 mg-Base	Odanacatib 10 mg-Base	Odanacatib 25 mg-Base
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	57	57	63
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	3.91 (-8.79 to 18.38)	50.81 (31.69 to 72.7)	2.33 (-10.63 to 17.16)	2.23 (-10.12 to 16.28)

End point values	Odanacatib 50 mg-Base			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-31.83 (-40.4 to -22.02)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-P1NP) compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 50 mg-Base
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [39]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-35.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-52.14
upper limit	-19.33

Notes:

[39] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-P1NP) compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 25 mg-Base

Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.161 [40]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.58
upper limit	17.23

Notes:

[40] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-P1NP) compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 10 mg-Base
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.99
upper limit	17.82

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-P1NP) compared to placebo over 12 months.

Comparison groups	Placebo-Base v Odanacatib 3 mg-Base
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	46.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	22.35
upper limit	71.44

Secondary: Percentage Change From Baseline in Total Hip BMD at 24 Months

End point title	Percentage Change From Baseline in Total Hip BMD at 24 Months

End point description:

Percentage change in total hip BMD (relative to baseline) at 24 months.

This analysis was performed at Month 24 using FAS Population with Last Observation Carried Forward (from extension data). No data was carried forward from the core to the extension period.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	57	59	65
Units: Percentage change				
least squares mean (confidence interval 95%)	-0.93 (-1.86 to -0.01)	-1.44 (-2.4 to -0.48)	1.82 (0.88 to 2.76)	2.55 (1.66 to 3.44)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: Percentage change				
least squares mean (confidence interval 95%)	3.16 (2.22 to 4.11)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Hip BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Total Hip BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1

Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [41]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.77
upper limit	5.42

Notes:

[41] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Hip BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Total Hip BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [42]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	3.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	4.77

Notes:

[42] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Hip BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Total Hip BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [43]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.75

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.43
upper limit	4.07

Notes:

[43] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Hip BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Total Hip BMD Density compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.536 [44]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.84
upper limit	0.83

Notes:

[44] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Secondary: Percentage Change From Baseline in Femoral Neck BMD at 24 Months

End point title	Percentage Change From Baseline in Femoral Neck BMD at 24 Months

End point description:

Percentage change in femoral neck BMD (relative to baseline) at 24 months.

This analysis was performed at Month 24 using FAS Population with Last Observation Carried Forward (from extension data). No data was carried forward from the core to the extension period.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	57	59	65
Units: Percentage change				
least squares mean (confidence interval 95%)	-0.85 (-1.85 to 0.16)	-1.25 (-2.29 to -0.22)	1.97 (0.95 to 2.98)	2.73 (1.76 to 3.69)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: Percentage change				
least squares mean (confidence interval 95%)	3.84 (2.82 to 4.86)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Femoral Neck BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Femoral Neck BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [45]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	4.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.25
upper limit	6.12

Notes:

[45] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Femoral Neck BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Femoral Neck BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1

Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [46]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	3.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.18
upper limit	4.97

Notes:

[46] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Femoral Neck BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Femoral Neck BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [47]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.39
upper limit	4.25

Notes:

[47] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Femoral Neck BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Femoral Neck BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.585 [48]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.41

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.85
upper limit	1.04

Notes:

[48] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure

Secondary: Percentage Change From Baseline in Tronchanter BMD at 24 Months

End point title	Percentage Change From Baseline in Tronchanter BMD at 24 Months

End point description:

Percentage change in trochanter BMD (relative to baseline) at 24 months.

This analysis was performed at Month 24 using FAS Population with Last Observation Carried Forward (from extension data). No data was carried forward from the core to the extension period.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	57	59	65
Units: Percent Change				
least squares mean (confidence interval 95%)	-0.81 (-2.15 to 0.53)	-0.85 (-2.23 to 0.53)	3.61 (2.26 to 4.97)	3.75 (2.46 to 5.04)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	58			
Units: Percent Change				
least squares mean (confidence interval 95%)	4.28 (2.92 to 5.65)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Trochanter BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Trochanter BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1

Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [49]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	5.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.18
upper limit	7.01

Notes:

[49] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Trochanter BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Trochanter BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [50]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	4.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.7
upper limit	6.42

Notes:

[50] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Trochanter BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Trochanter BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [51]
Method	ANCOVA
Parameter estimate	Difference in Least Square Means
Point estimate	4.43

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.52
upper limit	6.33

Notes:

[51] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Trochanter BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Trochanter BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.981 [52]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.97
upper limit	1.89

Notes:

[52] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Secondary: Percentage Change From Baseline in Total Body BMD at 24 Months

End point title	Percentage Change From Baseline in Total Body BMD at 24 Months

End point description:

Percentage change in total body BMD (relative to baseline) at 24 months.

This analysis was performed at Month 24 using FAS Population with Last Observation Carried Forward (from extension data). No data was carried forward from the core to the extension period.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	47	48	58
Units: Percentage change				
least squares mean (confidence interval 95%)	-1.54 (-2.42 to -0.66)	-2.7 (-3.66 to -1.74)	-1.35 (-2.29 to -0.4)	-0.43 (-1.29 to 0.43)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Percentage change				
least squares mean (confidence interval 95%)	0.19 (-0.73 to 1.11)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Body BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Total Body BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [53]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	1.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	3.01

Notes:

[53] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Body BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Total Body BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.028 [54]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	1.11

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.12
upper limit	2.34

Notes:

[54] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Body BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Total Body BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.804 [55]
Method	ANCOVA
Parameter estimate	Difference in Least Square Means
Point estimate	0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	1.49

Notes:

[55] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Total Body BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Total Body BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.46
upper limit	0.15

Secondary: Percentage Change From Baseline in Distal Forearm BMD at 24 Months

End point title	Percentage Change From Baseline in Distal Forearm BMD at 24 Months

End point description:

Percentage change in distal forearm BMD (relative to baseline) at 24 months.

This analysis was performed at Month 24 using FAS Population with Last Observation Carried Forward (from extension data). No data was carried forward from the core to the extension period.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	58	60	65
Units: Percentage change				
least squares mean (confidence interval 95%)	-2.75 (-3.83 to -1.66)	-5.7 (-6.8 to -4.59)	-1.22 (-2.31 to -0.13)	-0.65 (-1.7 to 0.39)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	57			
Units: Percentage change				
least squares mean (confidence interval 95%)	0.15 (-0.97 to 1.27)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Distal Forearm BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Distal Forearm BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [56]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.34
upper limit	4.46

Notes:

[56] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Distal Forearm BMD compared to placebo over 24 months. The secondary hypothesis states that MK0822 will increase Distal Forearm BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [57]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	2.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	3.6

Notes:

[57] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Distal Forearm BMD compared to placebo over 24 months. The secondary hypothesis states that MK0822 will increase Distal Forearm BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.094 [58]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	1.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	3.07

Notes:

[58] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on Distal Forearm BMD compared to placebo over 24 months. The secondary hypothesis states that odanacatib will increase Distal Forearm BMD compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-2.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.5
upper limit	-1.4

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary N-telopeptides of Type I Collagen [u-NTx]) at 24 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary N-telopeptides of Type I Collagen [u-NTx]) at 24 Months

End point description:

Back-transformation (geometric mean) of the least squares mean of the log-values percentage change from baseline, in biochemical marker of bone turnover (u- NTx) (relative to baseline) at 24 months

Analysis used a geometric mean percent change from baseline (back-transformation of a log-transformed fraction from baseline) at Month 24 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP protocol population did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	45	41	51
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-4.62 (-18.23 to 11.25)	12.89 (-4.93 to 34.05)	-40.57 (-50.32 to -28.9)	-38.3 (-47.48 to -27.51)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-51.83 (-60.05 to -41.91)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-NTx) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-NTx) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [59]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-47.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.51
upper limit	-29.9

Notes:

[59] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-NTx) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-NTx) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [60]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-33.67

Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.44
upper limit	-15.91

Notes:

[60] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-NTx) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-NTx) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [61]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-35.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.15
upper limit	-17.74

Notes:

[61] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-NTx) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-NTx) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.101 [62]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	17.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.78
upper limit	41.8

Notes:

[62] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handle by Hochberg procedure.

Secondary: Percentage Change in Biochemical Marker of Bone Turnover (Serum C-telopeptides of Type 1 Collagen [s-CTx]) at 24 Months

End point title	Percentage Change in Biochemical Marker of Bone Turnover (Serum C-telopeptides of Type 1 Collagen [s-CTx]) at 24 Months

End point description:

Back-transformation (geometric mean) of the least squares mean of the log-values percentage change from baseline, in biochemical marker of bone turnover (s-CTx)) (relative to baseline) at 24 months.

Analysis used a geometric mean percent change from baseline (back-transformation of a log-transformed fraction from baseline) at Month 24 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP protocol population did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	45	42	52
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	32.77 (13.28 to 55.61)	54.94 (29.83 to 84.92)	8.79 (-9.35 to 30.57)	-6.52 (-20.7 to 10.19)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-30.57 (-42.6 to -16.2)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (s-CTx) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (s-CTx) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1

Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [63]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-63.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-88.32
upper limit	-38.36

Notes:

[63] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (s-CTx) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (s-CTx) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.001 [64]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-39.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.4
upper limit	-13.18

Notes:

[64] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (s-CTx) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (s-CTx) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.124 [65]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-23.98

Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.04
upper limit	5.09

Notes:

[65] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (s-CTx) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (s-CTx) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	22.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.38
upper limit	56.73

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary Total Deoxypyridinolines [u-DPyr]) at 24 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary Total Deoxypyridinolines [u-DPyr]) at 24 Months

End point description:

Back-transformation (geometric mean) of the least squares mean of the log-values percentage change from baseline, in biochemical marker of bone turnover (u-DPyr) (relative to baseline) at 24 months.

Analysis used geometric mean percent change from baseline (back-transformation of a log-transformed fraction from baseline) at Month 24 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP protocol population did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	45	40	51
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-5.78 (-18.44 to 8.84)	15.96 (-1.29 to 36.23)	-7.57 (-22.03 to 9.57)	-14.3 (-26.3 to -0.33)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-22.49 (-34.96 to -7.64)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-DPyr) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-DPyr) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.015 [66]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-16.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.03
upper limit	2.61

Notes:

[66] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-DPyr) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-DPyr) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1

Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.246 [67]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-8.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.31
upper limit	10.29

Notes:

[67] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-DPyr) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-DPyr) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-1.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.66
upper limit	19.08

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone resorption (u-DPyr) compared to placebo over 24 months. The secondary hypothesis states that odanacatib will decrease biochemical indices of bone resorption (u-DPyr) over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	21.74

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.32
upper limit	44.81

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum Bone-specific Alkaline Phosphatase [s-BSAP]) at 24 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum Bone-specific Alkaline Phosphatase [s-BSAP]) at 24 Months

End point description:

Back-transformation (geometric mean) of the least squares mean of the log-values percentage change from baseline, in biochemical marker of bone turnover (s-BSAP) (relative to baseline) at 24 months.

Analysis used a geometric mean percent change from baseline (back-transformation of a log-transformed fraction from baseline) at Month 24 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP protocol population did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	47	42	53
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	3.38 (-4.94 to 12.44)	40.17 (27.8 to 53.73)	2.99 (-6.57 to 13.54)	10.62 (1.4 to 20.69)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-13.62 (-21.36 to -4.32)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg

weekly, and 50 mg weekly on biochemical indices of bone formation (s-BSAP) compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002 [68]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-16.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.84
upper limit	-4.44

Notes:

[68] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-BSAP) compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.852 [69]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	7.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.73
upper limit	20.21

Notes:

[69] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-BSAP) compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1

Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.69
upper limit	12.92

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-BSAP) compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	36.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.19
upper limit	52.38

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum N-terminal Propeptide of Type 1 Collagen [s-P1NP]) at 24 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum N-terminal Propeptide of Type 1 Collagen [s-P1NP]) at 24 Months

End point description:

Back-transformation (geometric mean) of the least squares mean of the log-values percentage change from baseline, in biochemical marker of bone turnover (s-P1NP) (relative to baseline) at 24 months.

Analysis used a geometric mean percent change from baseline (back-transformation of a log-transformed fraction from baseline) at Month 24 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP protocol population did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 24 months

End point values	Placebo-Ext 1	Odanacatib 3 mg-Ext 1	Odanacatib 10 mg-Ext 1	Odanacatib 25 mg-Ext 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	47	42	53
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	1.29 (-11.11 to 15.43)	50.52 (30.37 to 73.79)	9.07 (-6.28 to 26.93)	14.6 (0.08 to 31.23)

End point values	Odanacatib 50 mg-Ext 1			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: Geometric LS Mean percent change				
least squares mean (confidence interval 95%)	-20.2 (-31.49 to -7.05)			

Statistical analyses

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-P1NP) compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 50 mg-Ext 1
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.011 [70]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	-21.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.55
upper limit	-3.43

Notes:

[70] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-P1NP) compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 25 mg-Ext 1

Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.618 [71]
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	13.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	33.71

Notes:

[71] - Significance for secondary endpoints was only declared if there was also significance for the primary endpoint. Multiplicity was addressed through stepdown trend-test approach. Multiplicity for multiple endpoints was handled by Hochberg procedure.

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-P1NP) compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 10 mg-Ext 1
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	7.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.46
upper limit	29.01

Statistical analysis title	Difference in Least Squares Means

Statistical analysis description:

The secondary objective was to assess the effect of odanacatib 3 mg weekly, 10 mg weekly, 25 mg weekly, and 50 mg weekly on biochemical indices of bone formation (s-P1NP) compared to placebo over 24 months.

Comparison groups	Placebo-Ext 1 v Odanacatib 3 mg-Ext 1
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	other
Method	ANCOVA
Parameter estimate	Difference in Least Squares Means
Point estimate	49.23

Confidence interval	
level	95 %
sides	2-sided
lower limit	23.86
upper limit	74.59

Secondary: Percentage Change From Baseline in Total Hip BMD at 36 Months

End point title	Percentage Change From Baseline in Total Hip BMD at 36 Months

End point description:

Percentage change in Total Hip BMD (relative to baseline) at 36 Months.

This analysis was performed at Month 36 using the PP population, which included participants who took at least one dose of extension study medication and had the necessary follow-up information. Missing values were not imputed. No data were carried forward from Month 30 to 36.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	16	17	12
Units: Percent Change				
least squares mean (confidence interval 95%)	-0.77 (-2.92 to 1.38)	1.16 (-0.86 to 3.17)	-0.63 (-2.59 to 1.33)	2.75 (0.42 to 5.07)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	9	12	19
Units: Percent Change				
least squares mean (confidence interval 95%)	0.96 (-1.48 to 3.39)	4.61 (1.93 to 7.3)	1.64 (-0.69 to 3.97)	5.7 (3.85 to 7.54)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	17		
Units: Percent Change				
least squares mean (confidence interval	-0.48 (-2.56 to	5.83 (3.87 to		

95%)	1.6)	7.79)

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	6.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.44
upper limit	9.17

Secondary: Percentage Change From Baseline in Femoral Neck BMD at 36 Months

End point title	Percentage Change From Baseline in Femoral Neck BMD at 36 Months

End point description:

Percentage change in femoral neck BMD (relative to baseline) at 36 months.

This analysis was performed at Month 36 using the PP population, which included participants who took at least one dose of extension study medication and had the necessary follow-up information. Missing values were not imputed. No data were carried forward from Month 30 to 36.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	16	17	12
Units: Percent Change				
least squares mean (confidence interval 95%)	-0.52 (-2.67 to 1.63)	1.03 (-0.98 to 3.04)	-1.04 (-2.99 to 0.92)	2.26 (-0.06 to 4.59)

End point values	Odanacatib 10	Odanacatib 10	Odanacatib 25	Odanacatib 25

	mg/Placebo-Ext 2	mg/Odanacatib 50 mg-Ext 2	mg/Placebo-Ext 2	mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	9	12	19
Units: Percent Change				
least squares mean (confidence interval 95%)	-0.14 (-2.57 to 2.3)	5.06 (2.38 to 7.74)	0.8 (-1.52 to 3.13)	7.23 (5.38 to 9.07)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	17		
Units: Percent Change				
least squares mean (confidence interval 95%)	2.26 (0.19 to 4.34)	4.97 (3.01 to 6.93)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	2.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	5.57

Secondary: Percentage Change From Baseline in Trochanter BMD at 36 Months

End point title	Percentage Change From Baseline in Trochanter BMD at 36 Months

End point description:

Percentage change in trochanter BMD (relative to baseline) at 36 months.

This analysis was performed at Month 36 using the PP population, which included participants who took at least one dose of extension study medication and had the necessary follow-up information. Missing values were not imputed. No data were carried forward from Month 30 to 36.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	16	17	12
Units: Percent Change				
least squares mean (confidence interval 95%)	-0.46 (-3.71 to 2.79)	2.32 (-0.72 to 5.36)	-1.04 (-4 to 1.92)	4.53 (1.01 to 8.04)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	9	12	19
Units: Percent Change				
least squares mean (confidence interval 95%)	0.66 (-3.02 to 4.34)	8.21 (4.16 to 12.27)	1.14 (-2.38 to 4.65)	7.97 (5.18 to 10.76)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	17		
Units: Percent Change				
least squares mean (confidence interval 95%)	-0.69 (-3.83 to 2.46)	7.44 (4.48 to 10.41)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	8.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.8
upper limit	12.46

Secondary: Percentage Change From Baseline in Total Body BMD at 36 Months

End point title	Percentage Change From Baseline in Total Body BMD at 36 Months

End point description:

Percentage change in total body BMD (relative to baseline) at 36 months.

This analysis was performed at Month 36 using the PP population, which included participants who took at least one dose of extension study medication and had the necessary follow-up information. Missing values were not imputed. No data were carried forward from Month 30 to 36.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	16	13
Units: Percent Change				
least squares mean (confidence interval 95%)	0.13 (-2.12 to 2.38)	-2.2 (-4.45 to 0.05)	-3.63 (-5.74 to -1.52)	0.28 (-2.07 to 2.62)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	12	18
Units: Percent Change				
least squares mean (confidence interval 95%)	-2.28 (-4.71 to 0.15)	-1.22 (-4.03 to 1.58)	-0.85 (-3.29 to 1.58)	0.56 (-1.43 to 2.54)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	17		
Units: Percent Change				
least squares mean (confidence interval 95%)	-1.84 (-4.02 to 0.34)	-0.38 (-2.43 to 1.67)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	1.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.54
upper limit	4.46

Secondary: Percentage Change From Baseline in Distal Forearm BMD at 36 Months

End point title	Percentage Change From Baseline in Distal Forearm BMD at 36 Months

End point description:

Percentage change in distal forearm BMD (relative to baseline) at 36 months.

This analysis was performed at Month 36 using the PP population, which included participants who took at least one dose of extension study medication and had the necessary follow-up information. Missing values were not imputed. No data were carried forward from Month 30 to 36.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	16	13
Units: Percent Change				
least squares mean (confidence interval 95%)	-2.08 (-4.6 to 0.43)	-4.04 (-6.47 to -1.61)	-6.59 (-8.95 to -4.23)	-6.34 (-8.96 to -3.73)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	12	18
Units: Percent Change				
least squares mean (confidence interval 95%)	-1.74 (-4.46 to 0.97)	-3.74 (-6.71 to -0.76)	-2.39 (-5.11 to 0.32)	0.53 (-1.69 to 2.74)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	17		
Units: Percent Change				
least squares mean (confidence interval 95%)	-2.73 (-5.25 to -0.22)	-0.26 (-2.55 to 2.03)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Statistical analysis description: test	
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	2.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.93
upper limit	5.88

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary N-telopeptides of Type I Collagen [u-NTx]) at 36 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary N-telopeptides of Type I Collagen [u-NTx]) at 36 Months

End point description:

Geometric mean percentage change from baseline in biochemical marker of bone turnover (urinary N-telopeptides of Type I collagen [u-NTx]) at 36 months.

This analysis was geometric mean percent change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 36, using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	13	16
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	-17.43 (-39.06 to 11.86)	-55.12 (-66.51 to 39.85)	-11.9 (-35.76 to 20.83)	-57.17 (-67.75 to -43.12)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	11	10	18
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	-12.15 (-35.91 to 20.43)	-49.1 (-63.88 to -28.27)	14.26 (-20.17 to 63.53)	-52.11 (-63.33 to -37.45)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	17		
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	27.55 (-5.86 to 72.8)	-50.51 (-62.44 to -34.81)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	-78.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-119.2
upper limit	-36.92

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum C-telopeptides of Type 1 Collagen [s-CTx]) at 36 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum C-telopeptides of Type 1 Collagen [s-CTx]) at 36 Months

End point description:

Geometric mean percentage change from baseline in biochemical marker of bone turnover (serum C-telopeptides of Type 1 collagen [s-CTx]) at 36 Months.

This analysis was geometric mean percent change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 36 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	13	16
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	-0.09 (-28.93 to 40.46)	-41.3 (-57.74 to -18.47)	-4.69 (-33.13 to 35.85)	-44.62 (-59.72 to -23.88)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	11	9	18
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	18.24 (-16.98 to 68.41)	-26.26 (-49.81 to 8.33)	61.14 (5.5 to 146.12)	-36.71 (-53.09 to -14.6)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	17		
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	10.32 (-21.52 to 55.1)	-23.93 (-44.15 to 3.63)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	-34.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-78.7
upper limit	10.2

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary Total Deoxypyridinolines [u-DPyr]) at 36 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Urinary Total Deoxypyridinolines [u-DPyr]) at 36 Months

End point description:

Geometric mean percentage change from baseline in Biochemical marker of bone turnover (urinary total deoxypyridinolines [u-DPyr]) at 36 months.

This analysis was geometric mean percent change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 36 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	15	13	14
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	-18.69 (-41.68 to 13.36)	-14.95 (-38.27 to 17.18)	-7.82 (-34.76 to 30.26)	-26.27 (-47.1 to 2.76)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	11	10	18
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	-4.69 (-32.51 to 34.6)	0.43 (-31 to 46.19)	-9.16 (-38.64 to 34.48)	-16.41 (-37.59 to 11.97)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	17		
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	22.41 (-12.2 to 70.66)	-16.84 (-38.49 to 12.45)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Difference in Least Squares Means
Point estimate	-39.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-87.17
upper limit	8.68

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum Bone-specific Alkaline Phosphatase [s-BSAP]) at 36 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum Bone-specific Alkaline Phosphatase [s-BSAP]) at 36 Months

End point description:

Geometric mean percentage change from baseline, in biochemical marker of bone turnover (serum bone-specific alkaline phosphatase [s-BSAP]) at 36 months.

This analysis was geometric mean percentage change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 36 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	16	14	16
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	7.73 (-7.32 to 25.24)	10.86 (-3.69 to 27.62)	14.26 (-1.77 to 32.91)	9.13 (-5.2 to 25.62)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	11	12	18
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	12.95 (-3.41 to 32.08)	8.49 (-8.48 to 28.62)	33.74 (13.71 to 57.31)	11.12 (-2.67 to 26.86)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	17		
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	1.3 (-12.85 to 17.76)	17.9 (2.83 to 35.17)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	16.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.67
upper limit	38.85

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum N-terminal Propeptide of Type 1 Collagen [s-P1NP]) at 36 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum N-terminal Propeptide of Type 1 Collagen [s-P1NP]) at 36 Months

End point description:

Geometric mean percentage change from baseline in biochemical marker of bone turnover (serum N-terminal propeptide of Type 1 collagen [s-P1NP]) at 36 months.

This analysis was geometric mean percentage change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 36 using a PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	16	14	15
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	-20.79 (-40.08 to 4.72)	-18.79 (-37.44 to 5.42)	-13.11 (-34.35 to 15)	-21.08 (-39.75 to 3.37)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	11	12	18
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	8.58 (-18.75 to 45.11)	12.44 (-17.98 to 54.13)	22.57 (-9.27 to 65.59)	-8.14 (-28.14 to 17.42)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	17		
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	-0.77 (-24.94 to 31.18)	-6.2 (-27.2 to 20.86)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	-5.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.04
upper limit	31.18

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum Bone Tartrate-resistant Acid Phosphatase Isoform 5b [TRAP 5b]) at 36 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum Bone Tartrate-resistant Acid Phosphatase Isoform 5b [TRAP 5b]) at 36 Months

End point description:

Geometric mean percentage change from baseline in biochemical marker of bone turnover (serum bone tartrate-resistant acid phosphatase isoform 5b [TRAP 5b]) at 36 months.

This analysis was geometric mean percent change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 36 using the PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	10	12
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	52.98 (29.87 to 80.21)	52.37 (30.34 to 78.12)	33.25 (13.12 to 56.97)	59.37 (37.24 to 85.08)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	9	10	15
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	56.71 (33.04 to 84.6)	82.94 (53.93 to 117.42)	56.42 (32.79 to 84.26)	77.9 (55.63 to 103.36)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	15		
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	47.61 (25.3 to 73.88)	96.7 (72.08 to 124.85)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	49.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.37
upper limit	84.83

Secondary: Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum Cross-linked Carboxyterminal Telopeptides of Type I Collagen [1-CTP]) at 36 Months

End point title	Percentage Change From Baseline in Biochemical Marker of Bone Turnover (Serum Cross-linked Carboxyterminal Telopeptides of Type I Collagen [1-CTP]) at 36 Months

End point description:

Geometric mean percentage change from baseline in biochemical marker of bone turnover (serum cross-linked carboxyterminal telopeptides of Type I collagen [1-CTP]) at 36 Months.

This analysis was geometric mean percentage change from baseline (which is a back-transformation of a log-transformed fraction from baseline) at Month 36 using a PP population, from which participants with important protocol deviations and major protocol violators were excluded. The PP approach did not estimate missing data.

End point type	Secondary

End point timeframe:

Baseline and 36 months

End point values	Placebo/Placebo-Ext 2	Placebo/Odanacatib 50 mg-Ext 2	Odanacatib 3 mg/Placebo-Ext 2	Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	13	14	16
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	7.4 (-16.78 to 38.6)	193.91 (125.61 to 282.89)	1.67 (-21.41 to 31.53)	187.37 (126.25 to 264.99)

End point values	Odanacatib 10 mg/Placebo-Ext 2	Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Odanacatib 25 mg/Placebo-Ext 2	Odanacatib 25 mg/Odanacatib 50 mg-Ext 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	19
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	58.76 (20.27 to 109.56)	188.5 (116.34 to 284.74)	77.94 (33.46 to 137.24)	231.93 (166.74 to 313.05)

End point values	Odanacatib 50 mg/Placebo-Ext 2	Odanacatib 50 mg/Odanacatib 50 mg-Ext 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	18		
Units: Geometric Mean Percent Change				
least squares mean (confidence interval 95%)	27.2 (-0.61 to 62.79)	236.64 (168.69 to 321.76)		

Statistical analyses

Statistical analysis title	Difference in Least Squares Means
Comparison groups	Odanacatib 50 mg/Placebo-Ext 2 v Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least Squares Means
Point estimate	209.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	127.14
upper limit	291.73

Adverse events information

Timeframe for reporting adverse events:

Adverse Events data were collected up to 120 months (from start of study medication, up to 14 days after the last dose).

Adverse event reporting additional description:

The Safety Analysis was based on the All Participants as Treated (APaT) population, which included all participants who took at least one dose of study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.1

Reporting groups

Reporting group title	Years 1-2 Placebo/Placebo-Ext 1

Reporting group description:

One placebo tablet once a week

Reporting group title	Years 1-2 Odanacatib 3 mg/Odanacatib 3 mg-Ext 1

Reporting group description:

One odanacatib 3 mg tablet once a week

Reporting group title	Years 1-2 Odanacatib 10 mg/Odanacatib 10 mg-Ext 1

Reporting group description:

One odanacatib 10 mg tablet once a week

Reporting group title	Years 1-2 Odanacatib 25 mg/Odanacatib 25 mg-Ext 1

Reporting group description:

One odanacatib 25 mg tablet once a week

Reporting group title	Years 1-2 Odanacatib 50 mg/Odanacatib 50 mg-Ext 1

Reporting group description:

One odanacatib 50 mg tablet once a week

Reporting group title	Year 3 Placebo/Placebo-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants in this treatment group took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one placebo tablet once a week for 2 years.

Reporting group title	Year 3 Placebo/Odanacatib 50 mg-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one placebo tablet once a week for 2 years.

Reporting group title	Year 3 Odanacatib 3 mg/Placebo-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one 3 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Year 3 Odanacatib 3 mg/Odanacatib 50 mg-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one 3 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Year 3 Odanacatib 10 mg/Placebo-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one placebo tablet once a week. Before entering this extension, participants had taken one 10 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Year 3 Odanacatib 10 mg/Odanacatib 50 mg-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group took one 10 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Year 3 Odanacatib 25 mg/Placebo-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants in this treatment group took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one 25 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Year 3 Odanacatib 25 mg/Odanacatib 50 mg-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one 25 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Year 3 Odanacatib 50 mg/Placebo-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants in this treatment group took one placebo tablet once a week. Before entering this extension, participants in this treatment group had taken one 50 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Year 3 Odanacatib 50 mg/Odanacatib 50 mg-Ext 2

Reporting group description:

During this 12-month extension (Year 3), participants took one 50 mg tablet of odanacatib once a week. Before entering this extension, participants in this treatment group had taken one 50 mg tablet of odanacatib once a week for 2 years.

Reporting group title	Years 4-5 Combined Group A.1: Odanacatib 50 mg

Reporting group description:

Combined Group A.1 consists of participants who received odanacatib 50 mg once a week during Year 3. During this 24-month extension (Years 4-5), these participants continued to receive odanacatib 50 mg once a week.

Reporting group title	Years 4-5 Combined Group A.2: Odanacatib 50 mg

Reporting group description:

Combined Group A.2 consists of participants who received placebo or odanacatib 3 mg in Years 1, 2 and 3. During this 24-month extension (Years 4-5), these participants received odanacatib 50 mg once a week.

Reporting group title	Years 4-5 Combined Group A.3: Placebo

Reporting group description:

Combined Group A.3 consists of participants who, during this 24-month extension (Years 4-5), received placebo once a week.

Reporting group title	Years 6-10 Group A: Odanacatib 50 mg once weekly

Reporting group description:

Group A consists of a combination of participants who were treated with odanacatib 25 mg for 2 years, then odanacatib 50 mg for 8 years; and participants who were treated with odanacatib 50 mg for 10 years.

Reporting group title	Years 6-10 Group B: Odanacatib 50 mg once weekly

Reporting group description:

Group B consists of a combination participants who were treated with placebo for 2 years, then odanacatib 50 mg for 8 years; participants who were treated with odanacatib 3 mg for 2 years, then odanacatib 50 mg for 8 years; and participants who were treated with odanacatib 10 mg for 2 years, then odanacatib 50 mg for 8 years.

Reporting group title	Years 6-10 Group C: Odanacatib 50 mg once weekly

Reporting group description:

Group C consists of a combination of participants who were treated with placebo for 3 years, then odanacatib 50 mg for 7 years; and participants who were treated with odanacatib 3 mg for 2 years, then placebo for 1 year, then odanacatib 50 mg for 7 years.

Reporting group title	Years 6-10 Group D: Odanacatib 50 mg once weekly

Reporting group description:

Group D consists of a combination of participants who were treated with odanacatib 10 mg for 2 years, then placebo for 3 years, then odanacatib 50 mg for 5 years; participants who were treated with

odanacatib 25 mg for 5 years, then placebo for 3 years, then odanacatib 50 mg for 5 years; and participants who were treated with odanacatib 50 mg for 2 years, then placebo for 3 years, then odanacatib 50 mg for 5 years.

Serious adverse events	Years 1-2 Placebo/Placebo-Ext 1	Years 1-2 Odanacatib 3 mg/Odanacatib 3 mg-Ext 1	Years 1-2 Odanacatib 10 mg/Odanacatib 10 mg-Ext 1
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 83 (9.64%)	12 / 82 (14.63%)	10 / 77 (12.99%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal Cancer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal Cell Carcinoma			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer In Situ			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (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
Non-Hodgkin's Lymphoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary Thyroid Cancer			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer Metastatic			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Neoplasm			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurilemmoma Benign			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive breast carcinoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic Hypotension			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Genital Prolapse			
subjects affected / exposed	2 / 83 (2.41%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst torsion			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Uterine prolapse			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram ST-T Change			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight Decreased			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip Fracture			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Bile Leak			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated incisional hernia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention postoperative			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriospasm Coronary			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Congestive			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Occlusion			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (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
Myocardial Infarction			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Reversible Ischaemic Neurological Deficit			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Palsy			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve root compression			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Immune Thrombocytopenic Purpura			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo Positional			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular Hole			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal Fistula			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (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
Gastritis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus Hernia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (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
Peritonitis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Lower			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Sphincter Atony			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flatulence			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (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
Cholelithiasis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema Nodosum			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure Chronic			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (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 Pain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporotic Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigger Finger			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear Infection			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (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 Streptococcal			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (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 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Years 1-2 Odanacatib 25 mg/Odanacatib 25 mg-Ext 1	Years 1-2 Odanacatib 50 mg/Odanacatib 50 mg-Ext 1	Year 3 Placebo/Placebo-Ext 2
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 79 (11.39%)	14 / 78 (17.95%)	2 / 19 (10.53%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal Cancer			

subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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
Basal Cell Carcinoma			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Breast Cancer In Situ			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Non-Hodgkin's Lymphoma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Papillary Thyroid Cancer			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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
Sarcoma			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (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
Colon Cancer Metastatic			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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 Neoplasm			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Colon Adenoma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Neurilemmoma Benign			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Bowen's disease			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Gastric cancer			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Invasive breast carcinoma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Malignant melanoma			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Malignant melanoma in situ			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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 cancer			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Orthostatic Hypotension			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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
Hypotension			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
General disorders and administration site conditions			

Chest Pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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			
Genital Prolapse			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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 torsion			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Uterine prolapse			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Vaginal prolapse			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Pneumothorax			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Pulmonary embolism			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Investigations			
Electrocardiogram ST-T Change			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Weight Decreased			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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
Injury, poisoning and procedural complications			
Hip Fracture			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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
Joint Dislocation			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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 Bile Leak			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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
Head Injury			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Fall			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Rib Fracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Femur fracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Incarcerated incisional hernia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Scar			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Urinary retention postoperative			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriospasm Coronary			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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 Congestive			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Occlusion			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Myocardial Infarction			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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 Fibrillation			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Coronary Artery Disease			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Tachycardia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Palpitations			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Reversible Ischaemic Neurological Deficit			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Syncope			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Palsy			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Cerebral infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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

Cerebrovascular accident			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Dementia Alzheimer's type			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Headache			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Nerve root compression			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Paraesthesia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Presyncope			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Blood and lymphatic system disorders			
Immune Thrombocytopenic Purpura			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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

Vertigo Positional			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Macular Hole			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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
Retinal Detachment			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal Fistula			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Colitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Gastritis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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

Oesophagitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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
Pancreatitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Peritonitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Stomatitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Abdominal Pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Abdominal Pain Lower			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Anal Sphincter Atony			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Flatulence			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Gastrooesophageal Reflux Disease			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Nausea			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Vomiting			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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			
Cholecystitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Cholelithiasis			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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
Skin and subcutaneous tissue disorders			
Erythema Nodosum			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Renal and urinary disorders			

Nephrolithiasis			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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 Failure Chronic			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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			
Foot Deformity			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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
Osteoarthritis			
subjects affected / exposed	0 / 79 (0.00%)	2 / 78 (2.56%)	0 / 19 (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
Osteoporotic Fracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Trigger Finger			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Back Pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Bursitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Cellulitis			

subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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
Ear Infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Pneumonia Streptococcal			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Viral Infection			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (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
Pneumonia			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (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 Tract Infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Wound Infection			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Gastroenteritis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Pyelonephritis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Sialoadenitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Arthritis bacterial			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Bacterial sepsis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Year 3 Placebo/Odanacatib 50 mg-Ext 2	Year 3 Odanacatib 3 mg/Placebo-Ext 2	Year 3 Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 22 (9.09%)	3 / 18 (16.67%)	2 / 17 (11.76%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal Cancer			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (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
Breast Cancer			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Breast Cancer In Situ			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Non-Hodgkin's Lymphoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Papillary Thyroid Cancer			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Sarcoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Colon Cancer Metastatic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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 Neoplasm			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (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
Colon Adenoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Neurilemmoma Benign			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Bowen's disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Gastric cancer			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Invasive breast carcinoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Malignant melanoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Malignant melanoma in situ			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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 cancer			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Orthostatic Hypotension			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Hypotension			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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			
Genital Prolapse			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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 torsion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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

Uterine prolapse			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Vaginal prolapse			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Pneumothorax			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Pulmonary embolism			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Investigations			
Electrocardiogram ST-T Change			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Weight Decreased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Injury, poisoning and procedural complications			
Hip Fracture			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Joint Dislocation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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 Bile Leak			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Head Injury			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Wrist Fracture			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (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
Ankle Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Fall			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Rib Fracture			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Femur fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Incarcerated incisional hernia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Scar			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Urinary retention postoperative			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriospasm Coronary			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Congestive			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Coronary Artery Occlusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Myocardial Infarction			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Atrial Fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Coronary Artery Disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Tachycardia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Palpitations			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Reversible Ischaemic Neurological Deficit			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Syncope			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Facial Palsy			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Sciatica			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Cerebral infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Dementia Alzheimer's type			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Headache			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Nerve root compression			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Paraesthesia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Presyncope			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Blood and lymphatic system disorders			
Immune Thrombocytopenic Purpura			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Vertigo Positional			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Macular Hole			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Retinal Detachment			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal Fistula			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Colitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Gastritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Hiatus Hernia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Oesophagitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Peritonitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Stomatitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Abdominal Pain			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Abdominal Pain Lower			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Anal Sphincter Atony			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Flatulence			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Inguinal Hernia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Nausea			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Vomiting			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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			
Cholecystitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Cholelithiasis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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			
Erythema Nodosum			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Renal Failure Chronic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Osteoarthritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Osteoporotic Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Intervertebral Disc Degeneration			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Trigger Finger			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Lumbar Spinal Stenosis			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Bursitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Cellulitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Diverticulitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Ear Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Pneumonia Streptococcal			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Viral Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Pneumonia			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (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
Respiratory Tract Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (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
Wound Infection			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (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
Gastroenteritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Pyelonephritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Sialoadenitis			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Arthritis bacterial			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Bacterial sepsis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Year 3 Odanacatib 10 mg/Placebo-Ext 2	Year 3 Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Year 3 Odanacatib 25 mg/Placebo-Ext 2
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	1 / 19 (5.26%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal Cancer			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Breast Cancer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Breast Cancer In Situ			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Non-Hodgkin's Lymphoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Papillary Thyroid Cancer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Sarcoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Colon Cancer Metastatic			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 Neoplasm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Colon Adenoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Neurilemmoma Benign			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Bowen's disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Gastric cancer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Invasive breast carcinoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Malignant melanoma			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Malignant melanoma in situ			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 cancer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Orthostatic Hypotension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Hypotension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
General disorders and administration site conditions			

Chest Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
Genital Prolapse			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 torsion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Uterine prolapse			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Vaginal prolapse			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Pulmonary embolism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Investigations			
Electrocardiogram ST-T Change			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Weight Decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Injury, poisoning and procedural complications			
Hip Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Joint Dislocation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 Bile Leak			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Head Injury			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Wrist Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Fall			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Rib Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Femur fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Incarcerated incisional hernia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Scar			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Urinary retention postoperative			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriospasm Coronary			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Congestive			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Coronary Artery Occlusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Myocardial Infarction			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Atrial Fibrillation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Coronary Artery Disease			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Palpitations			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Reversible Ischaemic Neurological Deficit			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Syncope			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Facial Palsy			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Sciatica			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Cerebral infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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

Cerebrovascular accident			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Dementia Alzheimer's type			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Headache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Nerve root compression			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Paraesthesia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Presyncope			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Blood and lymphatic system disorders			
Immune Thrombocytopenic Purpura			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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

Vertigo Positional			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (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
Macular Hole			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Retinal Detachment			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal Fistula			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Colitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Gastritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Hiatus Hernia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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

Oesophagitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Peritonitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Stomatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Abdominal Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Abdominal Pain Lower			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Anal Sphincter Atony			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Flatulence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Gastrooesophageal Reflux Disease			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Inguinal Hernia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Nausea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Vomiting			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
Cholecystitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Cholelithiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
Erythema Nodosum			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Renal and urinary disorders			

Nephrolithiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Renal Failure Chronic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Osteoarthritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Osteoporotic Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigger Finger			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Back Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Bursitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Cellulitis			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Diverticulitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Ear Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Pneumonia Streptococcal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Viral Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Pneumonia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Wound Infection			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Gastroenteritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Pyelonephritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Sialoadenitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Arthritis bacterial			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Bacterial sepsis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Year 3 Odanacatib 25 mg/Odanacatib 50 mg-Ext 2	Year 3 Odanacatib 50 mg/Placebo-Ext 2	Year 3 Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 21 (19.05%)	2 / 18 (11.11%)	1 / 20 (5.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal Cancer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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	1 / 21 (4.76%)	1 / 18 (5.56%)	0 / 20 (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
Breast Cancer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Breast Cancer In Situ			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Non-Hodgkin's Lymphoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Papillary Thyroid Cancer			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Sarcoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Colon Cancer Metastatic			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 20 (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
Ovarian Neoplasm			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Colon Adenoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Neurilemmoma Benign			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Bowen's disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Gastric cancer			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Invasive breast carcinoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Malignant melanoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Malignant melanoma in situ			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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 cancer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Orthostatic Hypotension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Hypotension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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			
Genital Prolapse			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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 torsion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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

Uterine prolapse			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Vaginal prolapse			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Pneumothorax			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Pulmonary embolism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Investigations			
Electrocardiogram ST-T Change			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Weight Decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Injury, poisoning and procedural complications			
Hip Fracture			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Joint Dislocation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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 Bile Leak			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Head Injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Wrist Fracture			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Fall			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Rib Fracture			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Femur fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Incarcerated incisional hernia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Scar			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Urinary retention postoperative			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriospasm Coronary			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Congestive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Coronary Artery Occlusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Myocardial Infarction			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Atrial Fibrillation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Coronary Artery Disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Palpitations			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Reversible Ischaemic Neurological Deficit			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Syncope			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Facial Palsy			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Sciatica			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Cerebral infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Dementia Alzheimer's type			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Headache			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Nerve root compression			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Paraesthesia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Presyncope			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Blood and lymphatic system disorders			
Immune Thrombocytopenic Purpura			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (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
Vertigo Positional			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Macular Hole			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Retinal Detachment			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal Fistula			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Gastritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Hiatus Hernia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Oesophagitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Peritonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Stomatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Abdominal Pain			

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (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
Abdominal Pain Lower			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Sphincter Atony			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Flatulence			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Inguinal Hernia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Nausea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Vomiting			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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			
Cholecystitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Cholelithiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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			
Erythema Nodosum			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Renal Failure Chronic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Osteoarthritis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporotic Fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Trigger Finger			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Back Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Lumbar Spinal Stenosis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Bursitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Diverticulitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Ear Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Pneumonia Streptococcal			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Viral Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Respiratory Tract Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Wound Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Gastroenteritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Pyelonephritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Sialoadenitis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Arthritis bacterial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Bacterial sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (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

Serious adverse events	Years 4-5 Combined Group A.1: Odanacatib 50 mg	Years 4-5 Combined Group A.2: Odanacatib 50 mg	Years 4-5 Combined Group A.3: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 73 (21.92%)	2 / 27 (7.41%)	8 / 41 (19.51%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal Cancer			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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 / 73 (0.00%)	0 / 27 (0.00%)	3 / 41 (7.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Breast Cancer In Situ			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Non-Hodgkin's Lymphoma			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Papillary Thyroid Cancer			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Sarcoma			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Squamous Cell Carcinoma			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Colon Cancer Metastatic			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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 Neoplasm			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Colon Adenoma			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Neurilemmoma Benign			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (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
Bowen's disease			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Gastric cancer			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Invasive breast carcinoma			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Malignant melanoma			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Malignant melanoma in situ			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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 cancer			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Orthostatic Hypotension			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Hypotension			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
General disorders and administration site conditions			

Chest Pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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			
Genital Prolapse			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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 torsion			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Uterine prolapse			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Vaginal prolapse			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Pneumothorax			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Pulmonary embolism			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Investigations			
Electrocardiogram ST-T Change			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Weight Decreased			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Injury, poisoning and procedural complications			
Hip Fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Joint Dislocation			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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 Bile Leak			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Head Injury			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Fall			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Rib Fracture			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Femur fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Incarcerated incisional hernia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Scar			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Urinary retention postoperative			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriospasm Coronary			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Congestive			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Coronary Artery Occlusion			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Myocardial Infarction			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Atrial Fibrillation			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			

subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Tachycardia			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Palpitations			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Reversible Ischaemic Neurological Deficit			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Syncope			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Facial Palsy			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Sciatica			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Cerebral infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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

Cerebrovascular accident			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Dementia Alzheimer's type			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Headache			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Nerve root compression			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Paraesthesia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Presyncope			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Blood and lymphatic system disorders			
Immune Thrombocytopenic Purpura			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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

Vertigo Positional			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular Hole			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Retinal Detachment			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal Fistula			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Colitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Gastritis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Hiatus Hernia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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

Oesophagitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Peritonitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Stomatitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Abdominal Pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Lower			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Anal Sphincter Atony			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Flatulence			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Gastrooesophageal Reflux Disease			

subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Inguinal Hernia			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Nausea			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Vomiting			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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			
Cholecystitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Cholelithiasis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Skin and subcutaneous tissue disorders			
Erythema Nodosum			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Nephrolithiasis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Renal Failure Chronic			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Osteoarthritis			
subjects affected / exposed	4 / 73 (5.48%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporotic Fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Trigger Finger			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Back Pain			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Lumbar Spinal Stenosis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Bursitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Cellulitis			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Diverticulitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Ear Infection			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Pneumonia Streptococcal			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Viral Infection			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Pneumonia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Respiratory Tract Infection			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Wound Infection			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Gastroenteritis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Pyelonephritis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (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
Sialoadenitis			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (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
Arthritis bacterial			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Bacterial sepsis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Years 6-10 Group A: Odanacatib 50 mg once weekly	Years 6-10 Group B: Odanacatib 50 mg once weekly	Years 6-10 Group C: Odanacatib 50 mg once weekly
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 28 (28.57%)	14 / 34 (41.18%)	6 / 23 (26.09%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal Cancer			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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	2 / 28 (7.14%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Breast Cancer In Situ			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Non-Hodgkin's Lymphoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Papillary Thyroid Cancer			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Sarcoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Squamous Cell Carcinoma			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Colon Cancer Metastatic			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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 Neoplasm			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Colon Adenoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Neurilemmoma Benign			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Bowen's disease			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Invasive breast carcinoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Malignant melanoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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 cancer			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Orthostatic Hypotension			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Hypotension			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	0 / 23 (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
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Non-cardiac chest pain			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Reproductive system and breast disorders			
Genital Prolapse			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst torsion			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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

Uterine prolapse			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Pneumothorax			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Pulmonary embolism			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Investigations			
Electrocardiogram ST-T Change			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Weight Decreased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Injury, poisoning and procedural complications			
Hip Fracture			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Joint Dislocation			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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 Bile Leak			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Head Injury			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Wrist Fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Fall			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Rib Fracture			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Femur fracture			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated incisional hernia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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 retention postoperative			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriospasm Coronary			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Congestive			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Coronary Artery Occlusion			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Myocardial Infarction			

subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Atrial Fibrillation			
subjects affected / exposed	0 / 28 (0.00%)	2 / 34 (5.88%)	0 / 23 (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
Cardiac Failure			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Coronary Artery Disease			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Tachycardia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Palpitations			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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			
Reversible Ischaemic Neurological Deficit			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Syncope			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Facial Palsy			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Sciatica			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Cerebral infarction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Cerebrovascular accident			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Dementia Alzheimer's type			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Headache			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Nerve root compression			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Paraesthesia			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Presyncope			

subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Blood and lymphatic system disorders			
Immune Thrombocytopenic Purpura			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Vertigo Positional			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Macular Hole			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Retinal Detachment			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Anal Fistula			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Colitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Gastritis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Hiatus Hernia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Oesophagitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Peritonitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Stomatitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Abdominal Pain			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Abdominal Pain Lower			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Anal Sphincter Atony			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Flatulence			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Inguinal Hernia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Nausea			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Cholelithiasis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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			
Erythema Nodosum			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Renal Failure Chronic			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Endocrine disorders			
Hypoparathyroidism			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Foot Deformity			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Osteoarthritis			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	0 / 23 (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
Osteoporotic Fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Trigger Finger			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Back Pain			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Lumbar Spinal Stenosis			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Bursitis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Spinal pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Cellulitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Diverticulitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Ear Infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Pneumonia Streptococcal			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Viral Infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Pneumonia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Respiratory Tract Infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Wound Infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Gastroenteritis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Pyelonephritis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Arthritis bacterial			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (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
Bacterial sepsis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (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
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Years 6-10 Group D: Odanacatib 50 mg once weekly		
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 32 (37.50%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal Cancer			

subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Basal Cell Carcinoma				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Breast Cancer				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast Cancer In Situ				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-Hodgkin's Lymphoma				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Papillary Thyroid Cancer				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sarcoma				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous Cell Carcinoma				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colon Cancer Metastatic				

subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian Neoplasm				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon Adenoma				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neurilemmoma Benign				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bowen's disease				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric cancer				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Invasive breast carcinoma				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Invasive ductal breast carcinoma				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma				

subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma in situ				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma metastatic				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of skin				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Hypertension				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orthostatic Hypotension				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				

Chest Pain			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Genital Prolapse			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cyst			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cyst torsion			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine prolapse			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal prolapse			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Investigations				
Electrocardiogram ST-T Change				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Weight Decreased				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Hip Fracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint Dislocation				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar Vertebral Fracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Post Procedural Bile Leak				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head Injury				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrist Fracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankle Fracture				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rib Fracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incarcerated incisional hernia				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scar				

subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary retention postoperative				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Arteriospasm Coronary				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Failure Congestive				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary Artery Occlusion				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial Infarction				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial Fibrillation				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Failure				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary Artery Disease				

subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Palpitations				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Reversible Ischaemic Neurological Deficit				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial Palsy				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sciatica				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cerebrovascular accident			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dementia Alzheimer's type			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nerve root compression			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraesthesia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Immune Thrombocytopenic Purpura			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Vertigo Positional			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Macular Hole			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal Detachment			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Anal Fistula			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hiatus Hernia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Oesophagitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal Pain				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal Pain Lower				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anal Sphincter Atony				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flatulence				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal Reflux Disease				

subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal Hernia				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric Ulcer Haemorrhage				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Erythema Nodosum				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				

Nephrolithiasis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal Failure Chronic				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Hypoparathyroidism				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Foot Deformity				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal Pain				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoporotic Fracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral Disc Degeneration				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Musculoskeletal Chest Pain				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Trigger Finger				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back Pain				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar Spinal Stenosis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal pain				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				

subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ear Infection				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia Streptococcal				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral Infection				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory Tract Infection				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Infection				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Wound Infection				

subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sialoadenitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis bacterial				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis intestinal haemorrhagic				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				

subjects affected / exposed	0 / 32 (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	Years 1-2 Placebo/Placebo-Ext 1	Years 1-2 Odanacatib 3 mg/Odanacatib 3 mg-Ext 1	Years 1-2 Odanacatib 10 mg/Odanacatib 10 mg-Ext 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	68 / 83 (81.93%)	66 / 82 (80.49%)	67 / 77 (87.01%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences (all)	0	1	1
Ovarian Neoplasm			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	4 / 83 (4.82%)	7 / 82 (8.54%)	3 / 77 (3.90%)
occurrences (all)	4	7	3
Phlebitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Varicose Vein			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Calcinosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	1 / 83 (1.20%)	2 / 82 (2.44%)	0 / 77 (0.00%)
occurrences (all)	1	3	0
Chest Pain			
subjects affected / exposed	4 / 83 (4.82%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences (all)	8	1	1
Fatigue			
subjects affected / exposed	6 / 83 (7.23%)	2 / 82 (2.44%)	2 / 77 (2.60%)
occurrences (all)	6	2	2
Influenza Like Illness			
subjects affected / exposed	3 / 83 (3.61%)	1 / 82 (1.22%)	3 / 77 (3.90%)
occurrences (all)	3	1	5
Oedema Peripheral			
subjects affected / exposed	3 / 83 (3.61%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences (all)	3	1	1
Immune system disorders			
Allergy To Arthropod Sting			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast Mass			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Fibrocystic Breast Disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Pelvic Pain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Discomfort			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Oropharyngeal Pain			
subjects affected / exposed	2 / 83 (2.41%)	3 / 82 (3.66%)	3 / 77 (3.90%)
occurrences (all)	2	3	3
Asthma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Dyspnoea Exertional			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Emphysema			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	2	0	0
Cough			
subjects affected / exposed	2 / 83 (2.41%)	2 / 82 (2.44%)	2 / 77 (2.60%)
occurrences (all)	4	2	5
Psychiatric disorders			
Insomnia			
subjects affected / exposed	7 / 83 (8.43%)	3 / 82 (3.66%)	4 / 77 (5.19%)
occurrences (all)	7	4	4
Alcoholism			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	3 / 77 (3.90%)
occurrences (all)	0	0	3
Depression			
subjects affected / exposed	5 / 83 (6.02%)	4 / 82 (4.88%)	5 / 77 (6.49%)
occurrences (all)	5	4	5
Dysthymic Disorder			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Investigations			
Weight Increased			
subjects affected / exposed	4 / 83 (4.82%)	2 / 82 (2.44%)	3 / 77 (3.90%)
occurrences (all)	4	2	3
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 83 (1.20%)	3 / 82 (3.66%)	0 / 77 (0.00%)
occurrences (all)	1	4	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 83 (1.20%)	3 / 82 (3.66%)	2 / 77 (2.60%)
occurrences (all)	1	5	2
Blood 1,25-Dihydroxycholecalciferol Increased			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Blood Glucose Increased			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Blood Parathyroid Hormone Increased			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences (all)	0	1	1
Blood Pressure Increased			
subjects affected / exposed	0 / 83 (0.00%)	2 / 82 (2.44%)	0 / 77 (0.00%)
occurrences (all)	0	2	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Carotid Bruit			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Glucose Urine Present			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
High Density Lipoprotein Decreased			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences (all)	1	0	2
Weight Decreased			
subjects affected / exposed	2 / 83 (2.41%)	1 / 82 (1.22%)	2 / 77 (2.60%)
occurrences (all)	2	1	2
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 83 (0.00%)	2 / 82 (2.44%)	2 / 77 (2.60%)
occurrences (all)	0	3	2
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	0 / 83 (0.00%)	3 / 82 (3.66%)	2 / 77 (2.60%)
occurrences (all)	0	3	2
Arthropod Sting			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	5 / 83 (6.02%)	2 / 82 (2.44%)	5 / 77 (6.49%)
occurrences (all)	5	4	8
Epicondylitis			
subjects affected / exposed	1 / 83 (1.20%)	2 / 82 (2.44%)	0 / 77 (0.00%)
occurrences (all)	1	2	0
Fall			
subjects affected / exposed	2 / 83 (2.41%)	2 / 82 (2.44%)	1 / 77 (1.30%)
occurrences (all)	3	2	1
Humerus Fracture			

subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Limb Injury			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Muscle Strain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 83 (0.00%)	2 / 82 (2.44%)	0 / 77 (0.00%)
occurrences (all)	0	2	0
Procedural Pain			
subjects affected / exposed	1 / 83 (1.20%)	2 / 82 (2.44%)	0 / 77 (0.00%)
occurrences (all)	1	2	0
Radius Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Skull Fractured Base			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Spinal Compression Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Spinal Fracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Subdural Haematoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Thoracic Vertebral Fracture			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Tooth Fracture			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	1	1	0
Wrist Fracture			

subjects affected / exposed	2 / 83 (2.41%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	2	1	0
Laceration			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences (all)	0	0	2
Ligament sprain			
subjects affected / exposed	4 / 83 (4.82%)	1 / 82 (1.22%)	2 / 77 (2.60%)
occurrences (all)	4	1	2
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Atrial Flutter			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	11 / 83 (13.25%)	9 / 82 (10.98%)	10 / 77 (12.99%)
occurrences (all)	13	9	10
Memory Impairment			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			

subjects affected / exposed	2 / 83 (2.41%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences (all)	2	0	2
Sciatica			
subjects affected / exposed	2 / 83 (2.41%)	2 / 82 (2.44%)	0 / 77 (0.00%)
occurrences (all)	2	4	0
Somnolence			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Tension Headache			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences (all)	0	1	1
Tremor			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	1	0	2
Trigeminal Neuralgia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	4 / 83 (4.82%)	7 / 82 (8.54%)	8 / 77 (10.39%)
occurrences (all)	5	9	10
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	2 / 83 (2.41%)	1 / 82 (1.22%)	2 / 77 (2.60%)
occurrences (all)	2	1	2
Tympanosclerosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	4 / 83 (4.82%)	0 / 82 (0.00%)	3 / 77 (3.90%)
occurrences (all)	5	0	3
Vertigo Positional			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1

Eye disorders			
Cataract			
subjects affected / exposed	2 / 83 (2.41%)	2 / 82 (2.44%)	4 / 77 (5.19%)
occurrences (all)	2	2	4
Conjunctivitis Allergic			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Eye Pruritus			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Macular Degeneration			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	2 / 83 (2.41%)	5 / 82 (6.10%)	5 / 77 (6.49%)
occurrences (all)	2	5	5
Abdominal Pain			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences (all)	1	0	2
Anal Fissure			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	1	0	1
Constipation			
subjects affected / exposed	3 / 83 (3.61%)	8 / 82 (9.76%)	6 / 77 (7.79%)
occurrences (all)	3	8	7
Diarrhoea			
subjects affected / exposed	7 / 83 (8.43%)	4 / 82 (4.88%)	8 / 77 (10.39%)
occurrences (all)	7	5	8
Dry Mouth			
subjects affected / exposed	0 / 83 (0.00%)	2 / 82 (2.44%)	2 / 77 (2.60%)
occurrences (all)	0	2	2
Duodenal Ulcer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			

subjects affected / exposed	4 / 83 (4.82%)	2 / 82 (2.44%)	3 / 77 (3.90%)
occurrences (all)	6	3	4
Faecal Incontinence			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	1	0	1
Gastric Disorder			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Gastric Polyps			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Gastric Ulcer			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 83 (0.00%)	3 / 82 (3.66%)	0 / 77 (0.00%)
occurrences (all)	0	3	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 83 (1.20%)	3 / 82 (3.66%)	4 / 77 (5.19%)
occurrences (all)	1	3	4
Gingival Swelling			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Inguinal Hernia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Irritable Bowel Syndrome			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	3 / 77 (3.90%)
occurrences (all)	1	0	3
Mouth Ulceration			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	8 / 83 (9.64%)	4 / 82 (4.88%)	6 / 77 (7.79%)
occurrences (all)	8	6	7
Oesophagitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Rectal Haemorrhage			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	4 / 83 (4.82%)	3 / 82 (3.66%)	4 / 77 (5.19%)
occurrences (all)	7	4	6
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	3 / 77 (3.90%)
occurrences (all)	1	1	3
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	2 / 77 (2.60%)
occurrences (all)	0	1	2
Dermatitis Atopic			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Granuloma Annulare			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0

Lichen Planus			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences (all)	1	0	2
Psoriasis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	3	0	0
Rash			
subjects affected / exposed	7 / 83 (8.43%)	4 / 82 (4.88%)	5 / 77 (6.49%)
occurrences (all)	10	4	6
Rash Erythematous			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Rash Papular			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Sebaceous Hyperplasia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Skin Irritation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	3 / 77 (3.90%)
occurrences (all)	1	0	3
Urticaria			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Thyroiditis Chronic			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	3 / 83 (3.61%)	2 / 82 (2.44%)	4 / 77 (5.19%)
occurrences (all)	3	2	4
Arthralgia			
subjects affected / exposed	13 / 83 (15.66%)	12 / 82 (14.63%)	12 / 77 (15.58%)
occurrences (all)	24	16	13
Back Pain			
subjects affected / exposed	10 / 83 (12.05%)	17 / 82 (20.73%)	9 / 77 (11.69%)
occurrences (all)	12	19	11
Bone Pain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Dupuytren's Contracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Foot Deformity			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Joint Stiffness			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Monarthritis			

subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Muscle Contracture			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	4 / 83 (4.82%)	7 / 82 (8.54%)	7 / 77 (9.09%)
occurrences (all)	4	7	7
Muscular Weakness			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences (all)	0	0	2
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	5 / 83 (6.02%)	3 / 82 (3.66%)	5 / 77 (6.49%)
occurrences (all)	5	3	5
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Neck Pain			
subjects affected / exposed	3 / 83 (3.61%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences (all)	3	0	2
Osteoarthritis			
subjects affected / exposed	2 / 83 (2.41%)	5 / 82 (6.10%)	4 / 77 (5.19%)
occurrences (all)	2	5	5
Osteochondritis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Osteosclerosis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			

subjects affected / exposed	10 / 83 (12.05%)	8 / 82 (9.76%)	8 / 77 (10.39%)
occurrences (all)	13	10	8
Polyarthritis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	3 / 77 (3.90%)
occurrences (all)	1	0	5
Sacroiliitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Synovial Cyst			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	1 / 83 (1.20%)	6 / 82 (7.32%)	0 / 77 (0.00%)
occurrences (all)	1	6	0
Torticollis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	2 / 83 (2.41%)	4 / 82 (4.88%)	4 / 77 (5.19%)
occurrences (all)	5	6	5
Cellulitis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Chronic Sinusitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 83 (1.20%)	6 / 82 (7.32%)	3 / 77 (3.90%)
occurrences (all)	3	6	3

Ear Infection			
subjects affected / exposed	0 / 83 (0.00%)	2 / 82 (2.44%)	1 / 77 (1.30%)
occurrences (all)	0	4	1
Fungal Infection			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	1 / 83 (1.20%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	1	1	0
Gastroenteritis			
subjects affected / exposed	3 / 83 (3.61%)	2 / 82 (2.44%)	1 / 77 (1.30%)
occurrences (all)	4	3	1
Herpes Zoster			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	1 / 83 (1.20%)	3 / 82 (3.66%)	1 / 77 (1.30%)
occurrences (all)	1	3	1
Nasal Abscess			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	14 / 83 (16.87%)	9 / 82 (10.98%)	16 / 77 (20.78%)
occurrences (all)	20	13	20
Onychomycosis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	1 / 77 (1.30%)
occurrences (all)	0	1	1
Oral Candidiasis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Oral Herpes			
subjects affected / exposed	1 / 83 (1.20%)	2 / 82 (2.44%)	0 / 77 (0.00%)
occurrences (all)	1	2	0
Otitis Media Acute			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	4 / 83 (4.82%)	2 / 82 (2.44%)	4 / 77 (5.19%)
occurrences (all)	4	2	4
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Pyoderma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	1 / 83 (1.20%)	3 / 82 (3.66%)	1 / 77 (1.30%)
occurrences (all)	1	3	1
Sinusitis			
subjects affected / exposed	4 / 83 (4.82%)	4 / 82 (4.88%)	5 / 77 (6.49%)
occurrences (all)	4	4	6
Tooth Abscess			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences (all)	1	0	2
Tooth Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 82 (0.00%)	2 / 77 (2.60%)
occurrences (all)	0	0	2
Upper Respiratory Tract Infection			
subjects affected / exposed	9 / 83 (10.84%)	10 / 82 (12.20%)	7 / 77 (9.09%)
occurrences (all)	11	12	9
Urinary Tract Infection			
subjects affected / exposed	11 / 83 (13.25%)	6 / 82 (7.32%)	7 / 77 (9.09%)
occurrences (all)	17	7	7

Viral Infection			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	2	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	2	0	0
Eye infection			
subjects affected / exposed	1 / 83 (1.20%)	0 / 82 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 83 (1.20%)	3 / 82 (3.66%)	1 / 77 (1.30%)
occurrences (all)	1	3	1
Hyperlipidaemia			
subjects affected / exposed	0 / 83 (0.00%)	1 / 82 (1.22%)	0 / 77 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Years 1-2 Odanacatib 25 mg/Odanacatib 25 mg-Ext 1	Years 1-2 Odanacatib 50 mg/Odanacatib 50 mg-Ext 1	Year 3 Placebo/Placebo-Ext 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	67 / 79 (84.81%)	66 / 78 (84.62%)	17 / 19 (89.47%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Ovarian Neoplasm			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haematoma			

subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Hypertension			
subjects affected / exposed	8 / 79 (10.13%)	4 / 78 (5.13%)	0 / 19 (0.00%)
occurrences (all)	8	4	0
Phlebitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Varicose Vein			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	2	0	1
General disorders and administration site conditions			
Calcinosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	2 / 79 (2.53%)	2 / 78 (2.56%)	1 / 19 (5.26%)
occurrences (all)	2	2	1
Chest Pain			
subjects affected / exposed	2 / 79 (2.53%)	3 / 78 (3.85%)	2 / 19 (10.53%)
occurrences (all)	2	3	2
Fatigue			
subjects affected / exposed	1 / 79 (1.27%)	3 / 78 (3.85%)	1 / 19 (5.26%)
occurrences (all)	1	3	1
Influenza Like Illness			
subjects affected / exposed	2 / 79 (2.53%)	6 / 78 (7.69%)	0 / 19 (0.00%)
occurrences (all)	2	7	0
Oedema Peripheral			
subjects affected / exposed	2 / 79 (2.53%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	2	2	0
Immune system disorders			
Allergy To Arthropod Sting			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Breast Mass			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Fibrocystic Breast Disease			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pelvic Pain			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Vulvovaginal Discomfort			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain			
subjects affected / exposed	5 / 79 (6.33%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	5	1	0
Asthma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspnoea Exertional			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Emphysema			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	3 / 79 (3.80%)	3 / 78 (3.85%)	0 / 19 (0.00%)
occurrences (all)	4	3	0
Psychiatric disorders			

Insomnia			
subjects affected / exposed	3 / 79 (3.80%)	6 / 78 (7.69%)	0 / 19 (0.00%)
occurrences (all)	3	6	0
Alcoholism			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
Depression			
subjects affected / exposed	3 / 79 (3.80%)	3 / 78 (3.85%)	0 / 19 (0.00%)
occurrences (all)	3	3	0
Dysthymic Disorder			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Investigations			
Weight Increased			
subjects affected / exposed	5 / 79 (6.33%)	3 / 78 (3.85%)	0 / 19 (0.00%)
occurrences (all)	6	3	0
Alanine Aminotransferase Increased			
subjects affected / exposed	5 / 79 (6.33%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	7	3	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	4 / 79 (5.06%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	6	1	0
Blood 1,25-Dihydroxycholecalciferol Increased			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	1 / 19 (5.26%)
occurrences (all)	0	1	2
Blood Cholesterol Increased			
subjects affected / exposed	0 / 79 (0.00%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Blood Glucose Increased			

subjects affected / exposed	2 / 79 (2.53%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	3	2	0
Blood Parathyroid Hormone Increased			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Blood Pressure Increased			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Carotid Bruit			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Glucose Urine Present			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
High Density Lipoprotein Decreased			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	1 / 79 (1.27%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	1	3	0
Weight Decreased			
subjects affected / exposed	1 / 79 (1.27%)	4 / 78 (5.13%)	0 / 19 (0.00%)
occurrences (all)	1	4	0
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 79 (0.00%)	2 / 78 (2.56%)	1 / 19 (5.26%)
occurrences (all)	0	2	1
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Arthropod Sting			

subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	2 / 79 (2.53%)	3 / 78 (3.85%)	1 / 19 (5.26%)
occurrences (all)	3	3	1
Epicondylitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Humerus Fracture			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Limb Injury			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 79 (0.00%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	0	3	0
Radius Fracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skull Fractured Base			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Spinal Compression Fracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Spinal Fracture			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Subdural Haematoma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Thoracic Vertebral Fracture			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Tooth Fracture			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Wrist Fracture			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Laceration			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	3 / 79 (3.80%)	3 / 78 (3.85%)	0 / 19 (0.00%)
occurrences (all)	3	5	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Atrial Flutter			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Mitral Valve Prolapse			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 79 (1.27%)	5 / 78 (6.41%)	0 / 19 (0.00%)
occurrences (all)	2	5	0
Tachycardia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Headache			
subjects affected / exposed	9 / 79 (11.39%)	9 / 78 (11.54%)	0 / 19 (0.00%)
occurrences (all)	10	12	0
Memory Impairment			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Paraesthesia			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Somnolence			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tension Headache			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Tremor			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	3 / 79 (3.80%)	4 / 78 (5.13%)	0 / 19 (0.00%)
occurrences (all)	3	4	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Tinnitus			

subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Tympanosclerosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	1 / 79 (1.27%)	3 / 78 (3.85%)	1 / 19 (5.26%)
occurrences (all)	1	3	1
Vertigo Positional			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 79 (0.00%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	0	3	0
Conjunctivitis Allergic			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye Pruritus			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Macular Degeneration			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	0 / 79 (0.00%)	5 / 78 (6.41%)	0 / 19 (0.00%)
occurrences (all)	0	5	0
Abdominal Pain			
subjects affected / exposed	2 / 79 (2.53%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	4	2	0
Anal Fissure			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Constipation			

subjects affected / exposed	3 / 79 (3.80%)	1 / 78 (1.28%)	1 / 19 (5.26%)
occurrences (all)	3	1	1
Diarrhoea			
subjects affected / exposed	3 / 79 (3.80%)	7 / 78 (8.97%)	1 / 19 (5.26%)
occurrences (all)	3	10	1
Dry Mouth			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Duodenal Ulcer			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	3 / 79 (3.80%)	5 / 78 (6.41%)	0 / 19 (0.00%)
occurrences (all)	3	5	0
Faecal Incontinence			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	2 / 79 (2.53%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
Gastric Disorder			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastric Polyps			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastric Ulcer			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	5 / 79 (6.33%)	3 / 78 (3.85%)	2 / 19 (10.53%)
occurrences (all)	7	3	2
Gingival Swelling			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Inguinal Hernia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Mouth Ulceration			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	6 / 79 (7.59%)	5 / 78 (6.41%)	1 / 19 (5.26%)
occurrences (all)	7	7	1
Oesophagitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Rectal Haemorrhage			
subjects affected / exposed	2 / 79 (2.53%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	4	1	0
Toothache			
subjects affected / exposed	2 / 79 (2.53%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	2	2	0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 79 (5.06%)	1 / 78 (1.28%)	1 / 19 (5.26%)
occurrences (all)	4	1	1
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	2 / 79 (2.53%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Dermatitis Atopic			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Ecchymosis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Granuloma Annulare			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Lichen Planus			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Neurodermatitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	2 / 79 (2.53%)	3 / 78 (3.85%)	1 / 19 (5.26%)
occurrences (all)	2	3	1
Rash Erythematous			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Rash Papular			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Sebaceous Hyperplasia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Skin Irritation			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	2 / 79 (2.53%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Urticaria			
subjects affected / exposed	2 / 79 (2.53%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	2	0	3
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Thyroiditis Chronic			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	3 / 79 (3.80%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	3	2	0
Arthralgia			
subjects affected / exposed	14 / 79 (17.72%)	12 / 78 (15.38%)	3 / 19 (15.79%)
occurrences (all)	17	14	4
Back Pain			
subjects affected / exposed	14 / 79 (17.72%)	11 / 78 (14.10%)	2 / 19 (10.53%)
occurrences (all)	19	13	2
Bone Pain			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dupuytren's Contracture			

subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Foot Deformity			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Joint Stiffness			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Monarthritis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscle Contracture			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	3 / 79 (3.80%)	12 / 78 (15.38%)	1 / 19 (5.26%)
occurrences (all)	3	12	1
Muscular Weakness			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Musculoskeletal Chest Pain			
subjects affected / exposed	3 / 79 (3.80%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	3	1	0
Musculoskeletal Discomfort			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal Pain			
subjects affected / exposed	10 / 79 (12.66%)	4 / 78 (5.13%)	2 / 19 (10.53%)
occurrences (all)	11	4	2
Musculoskeletal Stiffness			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Neck Pain			
subjects affected / exposed	5 / 79 (6.33%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	5	0	0
Osteoarthritis			

subjects affected / exposed	4 / 79 (5.06%)	5 / 78 (6.41%)	1 / 19 (5.26%)
occurrences (all)	4	5	1
Osteochondritis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Osteosclerosis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
subjects affected / exposed	11 / 79 (13.92%)	3 / 78 (3.85%)	1 / 19 (5.26%)
occurrences (all)	11	5	1
Polyarthritis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Sacroiliitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Synovial Cyst			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Tendonitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Torticollis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	2 / 79 (2.53%)	1 / 78 (1.28%)	1 / 19 (5.26%)
occurrences (all)	2	2	1

Cellulitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Chronic Sinusitis			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 79 (1.27%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	2	2	0
Ear Infection			
subjects affected / exposed	1 / 79 (1.27%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Fungal Infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Furuncle			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	4 / 79 (5.06%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	4	1	0
Herpes Zoster			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	2 / 79 (2.53%)	3 / 78 (3.85%)	0 / 19 (0.00%)
occurrences (all)	2	3	0
Nasal Abscess			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Nasopharyngitis			
subjects affected / exposed	8 / 79 (10.13%)	14 / 78 (17.95%)	1 / 19 (5.26%)
occurrences (all)	10	23	1
Onychomycosis			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	1 / 19 (5.26%)
occurrences (all)	0	1	2

Oral Candidiasis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Oral Herpes			
subjects affected / exposed	2 / 79 (2.53%)	2 / 78 (2.56%)	0 / 19 (0.00%)
occurrences (all)	2	5	0
Otitis Media Acute			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	2 / 79 (2.53%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 79 (1.27%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Pyoderma			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Respiratory Tract Infection			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Rhinitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	4 / 79 (5.06%)	5 / 78 (6.41%)	0 / 19 (0.00%)
occurrences (all)	5	6	0
Tooth Abscess			
subjects affected / exposed	2 / 79 (2.53%)	3 / 78 (3.85%)	0 / 19 (0.00%)
occurrences (all)	2	3	0

Tooth Infection			
subjects affected / exposed	3 / 79 (3.80%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	7 / 79 (8.86%)	10 / 78 (12.82%)	1 / 19 (5.26%)
occurrences (all)	11	14	1
Urinary Tract Infection			
subjects affected / exposed	8 / 79 (10.13%)	12 / 78 (15.38%)	1 / 19 (5.26%)
occurrences (all)	10	15	1
Viral Infection			
subjects affected / exposed	4 / 79 (5.06%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	4	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye infection			
subjects affected / exposed	2 / 79 (2.53%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 79 (0.00%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	3 / 79 (3.80%)	0 / 78 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 79 (0.00%)	1 / 78 (1.28%)	0 / 19 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Year 3 Placebo/Odanacatib 50 mg-Ext 2	Year 3 Odanacatib 3 mg/Placebo-Ext 2	Year 3 Odanacatib 3 mg/Odanacatib 50 mg-Ext 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 22 (59.09%)	16 / 18 (88.89%)	14 / 17 (82.35%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ovarian Neoplasm			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Hypertension			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Phlebitis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Varicose Vein			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Calcinosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Chest Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Influenza Like Illness			

subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Oedema Peripheral			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy To Arthropod Sting			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast Mass			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Fibrocystic Breast Disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pelvic Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Discomfort			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dyspnoea Exertional			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Emphysema			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Alcoholism			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	2 / 22 (9.09%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Dysthymic Disorder			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Stress			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Investigations			
Weight Increased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Aspartate Aminotransferase Increased			

subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Blood 1,25-Dihydroxycholecalciferol Increased			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Blood Cholesterol Increased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood Glucose Increased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood Parathyroid Hormone Increased			
subjects affected / exposed	1 / 22 (4.55%)	1 / 18 (5.56%)	1 / 17 (5.88%)
occurrences (all)	1	1	1
Blood Pressure Increased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Carotid Bruit			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Glucose Urine Present			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
High Density Lipoprotein Decreased			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			

subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
White Blood Cells Urine Positive			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Arthropod Sting			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Epicondylitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Humerus Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Muscle Strain			
subjects affected / exposed	2 / 22 (9.09%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	2	1	0
Wound			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Procedural Pain			

subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Radius Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skull Fractured Base			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Spinal Compression Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Spinal Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Subdural Haematoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tooth Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Wrist Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	2 / 22 (9.09%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Ligament sprain			
subjects affected / exposed	2 / 22 (9.09%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Atrial Flutter			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 22 (9.09%)	1 / 18 (5.56%)	3 / 17 (17.65%)
occurrences (all)	2	1	3
Memory Impairment			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	2
Somnolence			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tension Headache			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Tremor			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tympanosclerosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Vertigo Positional			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Eye disorders			
Cataract			
subjects affected / exposed	1 / 22 (4.55%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Conjunctivitis Allergic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Eye Pruritus			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Macular Degeneration			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anal Fissure			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 22 (9.09%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Dry Mouth			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Duodenal Ulcer			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Faecal Incontinence			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Gastric Disorder			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Gastric Polyps			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastric Ulcer			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Gingival Swelling			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Inguinal Hernia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	1 / 17 (5.88%)
occurrences (all)	0	1	3
Mouth Ulceration			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Oesophagitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rectal Haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0

Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dermatitis Atopic			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Granuloma Annulare			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypertrichosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lichen Planus			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Neurodermatitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Psoriasis			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Rash Erythematous			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash Papular			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sebaceous Hyperplasia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin Irritation			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Skin Lesion			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thyroiditis Chronic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Arthralgia			

subjects affected / exposed	1 / 22 (4.55%)	1 / 18 (5.56%)	1 / 17 (5.88%)
occurrences (all)	1	1	1
Back Pain			
subjects affected / exposed	5 / 22 (22.73%)	1 / 18 (5.56%)	2 / 17 (11.76%)
occurrences (all)	5	1	2
Bone Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	3
Costochondritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dupuytren's Contracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Foot Deformity			
subjects affected / exposed	0 / 22 (0.00%)	2 / 18 (11.11%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Joint Stiffness			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Monarthritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle Contracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	2 / 22 (9.09%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	3	1	0
Muscular Weakness			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal Chest Pain			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal Pain			
subjects affected / exposed	1 / 22 (4.55%)	1 / 18 (5.56%)	1 / 17 (5.88%)
occurrences (all)	1	1	1
Musculoskeletal Stiffness			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Neck Pain			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Osteochondritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Osteosclerosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
subjects affected / exposed	3 / 22 (13.64%)	1 / 18 (5.56%)	2 / 17 (11.76%)
occurrences (all)	4	1	2
Polyarthritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Sacroiliitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Synovial Cyst			

subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tendonitis			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Torticollis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	2 / 22 (9.09%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	3	1	0
Cellulitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Chronic Sinusitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ear Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Fungal Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 22 (4.55%)	2 / 18 (11.11%)	0 / 17 (0.00%)
occurrences (all)	1	2	0

Herpes Zoster			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Nasal Abscess			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	4 / 22 (18.18%)	2 / 18 (11.11%)	2 / 17 (11.76%)
occurrences (all)	5	3	2
Onychomycosis			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Oral Candidiasis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral Herpes			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Otitis Media Acute			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Pyoderma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Respiratory Tract Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 18 (5.56%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Tooth Abscess			
subjects affected / exposed	1 / 22 (4.55%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Tooth Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 22 (0.00%)	3 / 18 (16.67%)	2 / 17 (11.76%)
occurrences (all)	0	4	2
Urinary Tract Infection			
subjects affected / exposed	2 / 22 (9.09%)	1 / 18 (5.56%)	2 / 17 (11.76%)
occurrences (all)	3	1	2
Viral Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Dyslipidaemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 22 (0.00%)	2 / 18 (11.11%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Hyperlipidaemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 18 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Year 3 Odanacatib 10 mg/Placebo-Ext 2	Year 3 Odanacatib 10 mg/Odanacatib 50 mg-Ext 2	Year 3 Odanacatib 25 mg/Placebo-Ext 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 18 (72.22%)	15 / 17 (88.24%)	15 / 19 (78.95%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Ovarian Neoplasm			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Varicose Vein			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Calcinosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chest Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Influenza Like Illness			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Oedema Peripheral			
subjects affected / exposed	1 / 18 (5.56%)	1 / 17 (5.88%)	1 / 19 (5.26%)
occurrences (all)	1	1	1
Immune system disorders			
Allergy To Arthropod Sting			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast Mass			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Fibrocystic Breast Disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pelvic Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspnoea Exertional			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Emphysema			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 18 (0.00%)	2 / 17 (11.76%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Alcoholism			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysthymic Disorder			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Investigations			
Weight Increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood 1,25-Dihydroxycholecalciferol Increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 18 (0.00%)	2 / 17 (11.76%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Blood Glucose Increased			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Blood Parathyroid Hormone Increased			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	5	0
Blood Pressure Increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Carotid Bruit			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Glucose Urine Present			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
High Density Lipoprotein Decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Arthropod Sting			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Humerus Fracture			

subjects affected / exposed	1 / 18 (5.56%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
Limb Injury			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Muscle Strain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Radius Fracture			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Skull Fractured Base			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Spinal Compression Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Spinal Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Subdural Haematoma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Tooth Fracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Wrist Fracture			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Laceration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Atrial Flutter			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 18 (5.56%)	1 / 17 (5.88%)	1 / 19 (5.26%)
occurrences (all)	1	1	1
Memory Impairment			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Paraesthesia			

subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Tension Headache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 18 (0.00%)	2 / 17 (11.76%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tympanosclerosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	2 / 18 (11.11%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Vertigo Positional			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0

Eye disorders			
Cataract			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	3
Conjunctivitis Allergic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye Pruritus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Macular Degeneration			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	1 / 18 (5.56%)	2 / 17 (11.76%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Anal Fissure			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dry Mouth			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Duodenal Ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Faecal Incontinence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastric Disorder			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Gastric Polyps			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Gastric Ulcer			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gingival Swelling			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Inguinal Hernia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Mouth Ulceration			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Oesophagitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	1 / 19 (5.26%)
occurrences (all)	0	2	1
Rectal Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dermatitis Atopic			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Granuloma Annulare			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Hyperkeratosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Lichen Planus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash Erythematous			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash Papular			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Sebaceous Hyperplasia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Skin Irritation			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Thyroiditis Chronic			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 18 (5.56%)	1 / 17 (5.88%)	2 / 19 (10.53%)
occurrences (all)	1	1	2
Back Pain			
subjects affected / exposed	1 / 18 (5.56%)	1 / 17 (5.88%)	4 / 19 (21.05%)
occurrences (all)	1	1	5
Bone Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dupuytren's Contracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Foot Deformity			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Joint Stiffness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Monarthritis			

subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Muscle Contracture			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscular Weakness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neck Pain			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Osteoarthritis			
subjects affected / exposed	2 / 18 (11.11%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
Osteochondritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Osteosclerosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Pain In Extremity			

subjects affected / exposed	3 / 18 (16.67%)	1 / 17 (5.88%)	3 / 19 (15.79%)
occurrences (all)	3	1	4
Polyarthritis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Sacroiliitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Synovial Cyst			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Torticollis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	1 / 19 (5.26%)
occurrences (all)	0	3	1
Cellulitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chronic Sinusitis			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1

Ear Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Fungal Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	1 / 18 (5.56%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Herpes Zoster			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Nasal Abscess			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 18 (16.67%)	0 / 17 (0.00%)	2 / 19 (10.53%)
occurrences (all)	3	0	2
Onychomycosis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oral Candidiasis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Oral Herpes			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Otitis Media Acute			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0

Pharyngitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Pyoderma			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	2 / 18 (11.11%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	2	0	1
Tooth Abscess			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Tooth Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Urinary Tract Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Viral Infection			
subjects affected / exposed	0 / 18 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	1 / 18 (5.56%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 18 (0.00%)	0 / 17 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1

Non-serious adverse events	Year 3 Odanacatib 25 mg/Odanacatib 50 mg-Ext 2	Year 3 Odanacatib 50 mg/Placebo-Ext 2	Year 3 Odanacatib 50 mg/Odanacatib 50 mg-Ext 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 21 (80.95%)	14 / 18 (77.78%)	15 / 20 (75.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ovarian Neoplasm			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haematoma			

subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 21 (0.00%)	2 / 18 (11.11%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Phlebitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Varicose Vein			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Calcinosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Chest Discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Chest Pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Fatigue			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Influenza Like Illness			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Oedema Peripheral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	3 / 20 (15.00%)
occurrences (all)	0	0	3
Immune system disorders			
Allergy To Arthropod Sting			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			

Breast Mass			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Fibrocystic Breast Disease			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Pelvic Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Discomfort			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dyspnoea Exertional			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Emphysema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Psychiatric disorders			

Insomnia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Alcoholism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dysthymic Disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
Weight Increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood 1,25-Dihydroxycholecalciferol Increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood Glucose Increased			

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Blood Parathyroid Hormone Increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Blood Pressure Increased			
subjects affected / exposed	2 / 21 (9.52%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Carotid Bruit			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Glucose Urine Present			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
High Density Lipoprotein Decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 21 (0.00%)	3 / 18 (16.67%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
Weight Decreased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthropod Sting			

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 21 (4.76%)	2 / 18 (11.11%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Humerus Fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Radius Fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skull Fractured Base			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Spinal Compression Fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Spinal Fracture			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Subdural Haematoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth Fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Wrist Fracture			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Laceration			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Atrial Flutter			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Headache			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Memory Impairment			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Sciatica			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tension Headache			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 21 (0.00%)	2 / 18 (11.11%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Tympanosclerosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vertigo Positional			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis Allergic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye Pruritus			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Macular Degeneration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	2 / 21 (9.52%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Anal Fissure			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Constipation			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	3 / 20 (15.00%)
occurrences (all)	0	1	0
Dry Mouth			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Duodenal Ulcer			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Faecal Incontinence			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Gastric Disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastric Polyps			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastric Ulcer			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Gastrooesophageal Reflux Disease			
subjects affected / exposed	2 / 21 (9.52%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	2	0	1
Gingival Swelling			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Inguinal Hernia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Mouth Ulceration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rectal Haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Dermatitis Atopic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Ecchymosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Granuloma Annulare			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hypertrichosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lichen Planus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Psoriasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 21 (0.00%)	2 / 18 (11.11%)	1 / 20 (5.00%)
occurrences (all)	0	2	3
Rash Erythematous			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Rash Papular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sebaceous Hyperplasia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Skin Irritation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thyroiditis Chronic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	3 / 21 (14.29%)	0 / 18 (0.00%)	3 / 20 (15.00%)
occurrences (all)	4	0	4
Back Pain			
subjects affected / exposed	2 / 21 (9.52%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Bone Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Costochondritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dupuytren's Contracture			

subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Foot Deformity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Joint Stiffness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Monarthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle Contracture			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Muscle Spasms			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	2 / 20 (10.00%)
occurrences (all)	1	1	2
Muscular Weakness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	3 / 21 (14.29%)	2 / 18 (11.11%)	0 / 20 (0.00%)
occurrences (all)	3	2	0
Musculoskeletal Stiffness			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Neck Pain			
subjects affected / exposed	2 / 21 (9.52%)	0 / 18 (0.00%)	4 / 20 (20.00%)
occurrences (all)	2	0	4
Osteoarthritis			

subjects affected / exposed	3 / 21 (14.29%)	1 / 18 (5.56%)	1 / 20 (5.00%)
occurrences (all)	3	2	1
Osteochondritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Osteosclerosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
subjects affected / exposed	2 / 21 (9.52%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Polyarthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sacroiliitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Synovial Cyst			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Torticollis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	1	1	0

Cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Chronic Sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
Ear Infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Fungal Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Herpes Zoster			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	2 / 21 (9.52%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Nasal Abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 21 (14.29%)	1 / 18 (5.56%)	1 / 20 (5.00%)
occurrences (all)	3	1	2
Onychomycosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

Oral Candidiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oral Herpes			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	1 / 20 (5.00%)
occurrences (all)	0	1	0
Otitis Media Acute			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pyoderma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tooth Abscess			
subjects affected / exposed	0 / 21 (0.00%)	1 / 18 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

Tooth Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 21 (9.52%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
Urinary Tract Infection			
subjects affected / exposed	3 / 21 (14.29%)	0 / 18 (0.00%)	2 / 20 (10.00%)
occurrences (all)	3	0	3
Viral Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 18 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Years 4-5 Combined Group A.1: Odanacatib 50 mg	Years 4-5 Combined Group A.2: Odanacatib 50 mg	Years 4-5 Combined Group A.3: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 73 (89.04%)	23 / 27 (85.19%)	33 / 41 (80.49%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Ovarian Neoplasm			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
Hypertension			
subjects affected / exposed	5 / 73 (6.85%)	2 / 27 (7.41%)	2 / 41 (4.88%)
occurrences (all)	6	2	2
Phlebitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Varicose Vein			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	2 / 41 (4.88%)
occurrences (all)	1	0	2
General disorders and administration site conditions			
Calcinosis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Chest Discomfort			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Chest Pain			
subjects affected / exposed	1 / 73 (1.37%)	1 / 27 (3.70%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
Fatigue			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
Influenza Like Illness			

subjects affected / exposed	1 / 73 (1.37%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Oedema Peripheral			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Immune system disorders			
Allergy To Arthropod Sting			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
Breast Mass			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Fibrocystic Breast Disease			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Pelvic Pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Discomfort			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	4 / 73 (5.48%)	0 / 27 (0.00%)	3 / 41 (7.32%)
occurrences (all)	4	0	3
Dyspnoea			
subjects affected / exposed	4 / 73 (5.48%)	0 / 27 (0.00%)	3 / 41 (7.32%)
occurrences (all)	4	0	3
Dyspnoea Exertional			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Emphysema			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	4 / 73 (5.48%)	0 / 27 (0.00%)	3 / 41 (7.32%)
occurrences (all)	4	0	3
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	2 / 41 (4.88%)
occurrences (all)	2	0	2
Alcoholism			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 73 (1.37%)	3 / 27 (11.11%)	1 / 41 (2.44%)
occurrences (all)	1	3	1
Dysthymic Disorder			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Investigations			
Weight Increased			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Aspartate Aminotransferase Increased			

subjects affected / exposed	1 / 73 (1.37%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Blood 1,25-Dihydroxycholecalciferol Increased			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Blood Cholesterol Increased			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
Blood Glucose Increased			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Blood Parathyroid Hormone Increased			
subjects affected / exposed	5 / 73 (6.85%)	3 / 27 (11.11%)	2 / 41 (4.88%)
occurrences (all)	13	5	3
Blood Pressure Increased			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	2 / 41 (4.88%)
occurrences (all)	1	0	2
Carotid Bruit			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Glucose Urine Present			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
High Density Lipoprotein Decreased			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Weight Decreased			

subjects affected / exposed	1 / 73 (1.37%)	1 / 27 (3.70%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Arthropod Sting			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	1 / 41 (2.44%)
occurrences (all)	0	1	2
Contusion			
subjects affected / exposed	4 / 73 (5.48%)	0 / 27 (0.00%)	2 / 41 (4.88%)
occurrences (all)	6	0	2
Epicondylitis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	3 / 73 (4.11%)	0 / 27 (0.00%)	2 / 41 (4.88%)
occurrences (all)	4	0	2
Humerus Fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Muscle Strain			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	2 / 41 (4.88%)
occurrences (all)	0	0	2
Wound			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			

subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Radius Fracture			
subjects affected / exposed	1 / 73 (1.37%)	2 / 27 (7.41%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
Skull Fractured Base			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Spinal Compression Fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Spinal Fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Subdural Haematoma			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Tooth Fracture			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Wrist Fracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	1 / 73 (1.37%)	1 / 27 (3.70%)	3 / 41 (7.32%)
occurrences (all)	1	1	3
Ligament sprain			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0

Atrial Flutter			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 73 (2.74%)	2 / 27 (7.41%)	1 / 41 (2.44%)
occurrences (all)	2	2	2
Memory Impairment			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Paraesthesia			
subjects affected / exposed	3 / 73 (4.11%)	1 / 27 (3.70%)	2 / 41 (4.88%)
occurrences (all)	3	1	3
Sciatica			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	3	0	1
Somnolence			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Tension Headache			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Tremor			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Tympanosclerosis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vertigo Positional			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	2 / 73 (2.74%)	2 / 27 (7.41%)	3 / 41 (7.32%)
occurrences (all)	2	4	3
Conjunctivitis Allergic			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Eye Pruritus			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Macular Degeneration			

subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	1 / 73 (1.37%)	2 / 27 (7.41%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
Abdominal Pain			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	2 / 41 (4.88%)
occurrences (all)	1	0	3
Anal Fissure			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	3 / 73 (4.11%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	4	1	0
Diarrhoea			
subjects affected / exposed	2 / 73 (2.74%)	3 / 27 (11.11%)	0 / 41 (0.00%)
occurrences (all)	3	3	0
Dry Mouth			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Duodenal Ulcer			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	3 / 73 (4.11%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	4	0	0
Faecal Incontinence			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Gastric Disorder			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0

Gastric Polyps			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Gastric Ulcer			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	3 / 73 (4.11%)	2 / 27 (7.41%)	0 / 41 (0.00%)
occurrences (all)	3	2	0
Gingival Swelling			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Inguinal Hernia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Irritable Bowel Syndrome			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Mouth Ulceration			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 73 (1.37%)	2 / 27 (7.41%)	1 / 41 (2.44%)
occurrences (all)	1	2	1
Oesophagitis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Rectal Haemorrhage			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Toothache			
subjects affected / exposed	4 / 73 (5.48%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	4	0	0

Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 73 (2.74%)	1 / 27 (3.70%)	1 / 41 (2.44%)
occurrences (all)	2	1	1
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Dermatitis Atopic			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Granuloma Annulare			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Hypertrichosis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Lichen Planus			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 73 (1.37%)	1 / 27 (3.70%)	1 / 41 (2.44%)
occurrences (all)	2	1	1
Psoriasis			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 73 (1.37%)	1 / 27 (3.70%)	1 / 41 (2.44%)
occurrences (all)	2	1	1
Rash Erythematous			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Rash Papular			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Sebaceous Hyperplasia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Skin Irritation			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	1 / 41 (2.44%)
occurrences (all)	0	1	2
Urticaria			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	2
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Thyroiditis Chronic			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	2 / 73 (2.74%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Arthralgia			

subjects affected / exposed	9 / 73 (12.33%)	4 / 27 (14.81%)	6 / 41 (14.63%)
occurrences (all)	13	4	8
Back Pain			
subjects affected / exposed	8 / 73 (10.96%)	5 / 27 (18.52%)	1 / 41 (2.44%)
occurrences (all)	11	7	1
Bone Pain			
subjects affected / exposed	1 / 73 (1.37%)	1 / 27 (3.70%)	1 / 41 (2.44%)
occurrences (all)	1	1	1
Bursitis			
subjects affected / exposed	2 / 73 (2.74%)	2 / 27 (7.41%)	1 / 41 (2.44%)
occurrences (all)	2	2	1
Costochondritis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Dupuytren's Contracture			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Foot Deformity			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Joint Stiffness			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Monarthritis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Muscle Contracture			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Muscle Spasms			
subjects affected / exposed	3 / 73 (4.11%)	1 / 27 (3.70%)	1 / 41 (2.44%)
occurrences (all)	3	1	1
Muscular Weakness			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal Chest Pain			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	4 / 73 (5.48%)	1 / 27 (3.70%)	6 / 41 (14.63%)
occurrences (all)	5	1	6
Musculoskeletal Stiffness			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Neck Pain			
subjects affected / exposed	3 / 73 (4.11%)	2 / 27 (7.41%)	1 / 41 (2.44%)
occurrences (all)	3	2	1
Osteoarthritis			
subjects affected / exposed	6 / 73 (8.22%)	2 / 27 (7.41%)	1 / 41 (2.44%)
occurrences (all)	7	3	2
Osteochondritis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Osteosclerosis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Pain In Extremity			
subjects affected / exposed	12 / 73 (16.44%)	4 / 27 (14.81%)	2 / 41 (4.88%)
occurrences (all)	15	5	2
Polyarthritis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Rotator Cuff Syndrome			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	2	0	1
Sacroiliitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Synovial Cyst			

subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Torticollis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	4 / 73 (5.48%)	4 / 27 (14.81%)	4 / 41 (9.76%)
occurrences (all)	7	4	4
Cellulitis			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Chronic Sinusitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Ear Infection			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Fungal Infection			
subjects affected / exposed	0 / 73 (0.00%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Furuncle			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	2 / 73 (2.74%)	2 / 27 (7.41%)	0 / 41 (0.00%)
occurrences (all)	2	2	0

Herpes Zoster			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	4 / 73 (5.48%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	4	0	0
Nasal Abscess			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	13 / 73 (17.81%)	6 / 27 (22.22%)	10 / 41 (24.39%)
occurrences (all)	16	13	13
Onychomycosis			
subjects affected / exposed	2 / 73 (2.74%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Oral Candidiasis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Oral Herpes			
subjects affected / exposed	2 / 73 (2.74%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Otitis Media Acute			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	1 / 73 (1.37%)	1 / 27 (3.70%)	2 / 41 (4.88%)
occurrences (all)	1	1	3
Pyoderma			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0

Respiratory Tract Infection			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	3 / 73 (4.11%)	3 / 27 (11.11%)	2 / 41 (4.88%)
occurrences (all)	3	5	2
Tooth Abscess			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Tooth Infection			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 73 (4.11%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	4	0	1
Urinary Tract Infection			
subjects affected / exposed	10 / 73 (13.70%)	4 / 27 (14.81%)	2 / 41 (4.88%)
occurrences (all)	12	4	3
Viral Infection			
subjects affected / exposed	2 / 73 (2.74%)	1 / 27 (3.70%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	1 / 73 (1.37%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			

Dyslipidaemia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	2 / 73 (2.74%)	2 / 27 (7.41%)	0 / 41 (0.00%)
occurrences (all)	2	2	0
Hyperlipidaemia			
subjects affected / exposed	0 / 73 (0.00%)	0 / 27 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Years 6-10 Group A: Odanacatib 50 mg once weekly	Years 6-10 Group B: Odanacatib 50 mg once weekly	Years 6-10 Group C: Odanacatib 50 mg once weekly
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 28 (96.43%)	34 / 34 (100.00%)	23 / 23 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Ovarian Neoplasm			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	3 / 28 (10.71%)	6 / 34 (17.65%)	5 / 23 (21.74%)
occurrences (all)	3	7	5
Phlebitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Varicose Vein			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1

General disorders and administration site conditions			
Calcinosis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Chest Pain			
subjects affected / exposed	2 / 28 (7.14%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	3	1	2
Fatigue			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	1	1	1
Oedema Peripheral			
subjects affected / exposed	1 / 28 (3.57%)	2 / 34 (5.88%)	2 / 23 (8.70%)
occurrences (all)	2	2	3
Immune system disorders			
Allergy To Arthropod Sting			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast Mass			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Fibrocystic Breast Disease			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pelvic Pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Discomfort			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	3 / 28 (10.71%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	3	0	1
Dyspnoea Exertional			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Emphysema			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 28 (0.00%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 28 (7.14%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	2	1	1
Alcoholism			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	1	1	1
Depression			
subjects affected / exposed	4 / 28 (14.29%)	3 / 34 (8.82%)	2 / 23 (8.70%)
occurrences (all)	5	3	4
Dysthymic Disorder			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Investigations			
Weight Increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	4 / 23 (17.39%)
occurrences (all)	0	0	4
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	4 / 23 (17.39%)
occurrences (all)	0	0	4
Blood 1,25-Dihydroxycholecalciferol Increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood Cholesterol Increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood Glucose Increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood Parathyroid Hormone Increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood Pressure Increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood Triglycerides Increased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Carotid Bruit			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Glucose Urine Present			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
High Density Lipoprotein Decreased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
subjects affected / exposed	0 / 28 (0.00%)	2 / 34 (5.88%)	2 / 23 (8.70%)
occurrences (all)	0	3	2
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	1	0
Arthropod Sting			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	3 / 28 (10.71%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	3	0	2
Epicondylitis			
subjects affected / exposed	2 / 28 (7.14%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Fall			
subjects affected / exposed	3 / 28 (10.71%)	4 / 34 (11.76%)	5 / 23 (21.74%)
occurrences (all)	12	8	6
Humerus Fracture			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Muscle Strain			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Radius Fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skull Fractured Base			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Spinal Compression Fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Spinal Fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Subdural Haematoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tooth Fracture			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	2 / 23 (8.70%)
occurrences (all)	1	2	4
Wrist Fracture			

subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	1	0
Laceration			
subjects affected / exposed	1 / 28 (3.57%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences (all)	1	3	1
Ligament sprain			
subjects affected / exposed	1 / 28 (3.57%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	1	2	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Atrial Flutter			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 28 (7.14%)	1 / 34 (2.94%)	3 / 23 (13.04%)
occurrences (all)	3	1	4
Memory Impairment			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Paraesthesia			

subjects affected / exposed	2 / 28 (7.14%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	2	1	1
Sciatica			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tension Headache			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 28 (7.14%)	3 / 34 (8.82%)	2 / 23 (8.70%)
occurrences (all)	2	3	2
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 28 (0.00%)	2 / 34 (5.88%)	2 / 23 (8.70%)
occurrences (all)	0	3	2
Tympanosclerosis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 28 (0.00%)	5 / 34 (14.71%)	1 / 23 (4.35%)
occurrences (all)	0	7	1
Vertigo Positional			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Eye disorders			
Cataract			
subjects affected / exposed	0 / 28 (0.00%)	6 / 34 (17.65%)	6 / 23 (26.09%)
occurrences (all)	0	9	10
Conjunctivitis Allergic			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Eye Pruritus			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Macular Degeneration			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	1	1	1
Abdominal Pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Anal Fissure			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	2 / 28 (7.14%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences (all)	3	2	2
Diarrhoea			
subjects affected / exposed	2 / 28 (7.14%)	2 / 34 (5.88%)	4 / 23 (17.39%)
occurrences (all)	2	3	5
Dry Mouth			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Duodenal Ulcer			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			

subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	4 / 23 (17.39%)
occurrences (all)	0	1	4
Faecal Incontinence			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Gastric Disorder			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastric Polyps			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastric Ulcer			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 28 (3.57%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences (all)	1	2	1
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	2 / 23 (8.70%)
occurrences (all)	1	0	2
Gingival Swelling			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Inguinal Hernia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Irritable Bowel Syndrome			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Mouth Ulceration			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Nausea			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 28 (0.00%)	3 / 34 (8.82%)	0 / 23 (0.00%)
occurrences (all)	0	3	0
Rectal Haemorrhage			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	1	0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	2 / 28 (7.14%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
Dermatitis Atopic			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	3
Ecchymosis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Granuloma Annulare			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Hypertrichosis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Lichen Planus			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 28 (7.14%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Psoriasis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 28 (0.00%)	2 / 34 (5.88%)	2 / 23 (8.70%)
occurrences (all)	0	2	2
Rash Erythematous			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rash Papular			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Sebaceous Hyperplasia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skin Irritation			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skin Lesion			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	2
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Thyroiditis Chronic			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 28 (3.57%)	2 / 34 (5.88%)	2 / 23 (8.70%)
occurrences (all)	1	2	2
Arthralgia			
subjects affected / exposed	5 / 28 (17.86%)	4 / 34 (11.76%)	8 / 23 (34.78%)
occurrences (all)	10	4	8
Back Pain			
subjects affected / exposed	6 / 28 (21.43%)	7 / 34 (20.59%)	5 / 23 (21.74%)
occurrences (all)	6	9	7
Bone Pain			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	1	1	1
Costochondritis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dupuytren's Contracture			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	1	0
Foot Deformity			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Joint Stiffness			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Monarthritis			

subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Muscle Contracture			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	2 / 23 (8.70%)
occurrences (all)	1	1	2
Muscular Weakness			
subjects affected / exposed	0 / 28 (0.00%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences (all)	0	2	1
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal Discomfort			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	3 / 28 (10.71%)	4 / 34 (11.76%)	5 / 23 (21.74%)
occurrences (all)	6	4	6
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Neck Pain			
subjects affected / exposed	0 / 28 (0.00%)	3 / 34 (8.82%)	3 / 23 (13.04%)
occurrences (all)	0	4	4
Osteoarthritis			
subjects affected / exposed	3 / 28 (10.71%)	5 / 34 (14.71%)	2 / 23 (8.70%)
occurrences (all)	3	6	2
Osteochondritis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Osteosclerosis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Pain In Extremity			

subjects affected / exposed	6 / 28 (21.43%)	1 / 34 (2.94%)	2 / 23 (8.70%)
occurrences (all)	6	1	3
Polyarthritis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Sacroiliitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Synovial Cyst			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	2 / 28 (7.14%)	3 / 34 (8.82%)	2 / 23 (8.70%)
occurrences (all)	2	3	2
Torticollis			
subjects affected / exposed	2 / 28 (7.14%)	3 / 34 (8.82%)	2 / 23 (8.70%)
occurrences (all)	2	3	2
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	3 / 28 (10.71%)	5 / 34 (14.71%)	5 / 23 (21.74%)
occurrences (all)	4	5	9
Cellulitis			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Chronic Sinusitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	2 / 23 (8.70%)
occurrences (all)	1	0	2

Ear Infection			
subjects affected / exposed	1 / 28 (3.57%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	1	2	0
Fungal Infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Herpes Zoster			
subjects affected / exposed	1 / 28 (3.57%)	2 / 34 (5.88%)	1 / 23 (4.35%)
occurrences (all)	1	2	1
Influenza			
subjects affected / exposed	1 / 28 (3.57%)	4 / 34 (11.76%)	0 / 23 (0.00%)
occurrences (all)	1	4	0
Nasal Abscess			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	7 / 28 (25.00%)	8 / 34 (23.53%)	5 / 23 (21.74%)
occurrences (all)	9	15	9
Onychomycosis			
subjects affected / exposed	0 / 28 (0.00%)	2 / 34 (5.88%)	3 / 23 (13.04%)
occurrences (all)	0	3	4
Oral Candidiasis			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Oral Herpes			
subjects affected / exposed	2 / 28 (7.14%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	2	1	0
Otitis Media Acute			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1

Pharyngitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
Pharyngitis Streptococcal			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	3	1
Pneumonia			
subjects affected / exposed	0 / 28 (0.00%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	0	3	1
Pyoderma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Respiratory Tract Infection			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	2
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 28 (3.57%)	2 / 34 (5.88%)	0 / 23 (0.00%)
occurrences (all)	1	2	0
Sinusitis			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	4 / 23 (17.39%)
occurrences (all)	2	1	4
Tooth Abscess			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Tooth Infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 28 (7.14%)	3 / 34 (8.82%)	2 / 23 (8.70%)
occurrences (all)	7	5	2
Urinary Tract Infection			
subjects affected / exposed	9 / 28 (32.14%)	9 / 34 (26.47%)	6 / 23 (26.09%)
occurrences (all)	15	19	20

Viral Infection			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	1	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 28 (0.00%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Dyslipidaemia			
subjects affected / exposed	1 / 28 (3.57%)	1 / 34 (2.94%)	0 / 23 (0.00%)
occurrences (all)	1	1	0
Hypercholesterolaemia			
subjects affected / exposed	3 / 28 (10.71%)	1 / 34 (2.94%)	1 / 23 (4.35%)
occurrences (all)	3	1	1
Hyperlipidaemia			
subjects affected / exposed	1 / 28 (3.57%)	0 / 34 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Years 6-10 Group D: Odanacatib 50 mg once weekly		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 32 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Ovarian Neoplasm			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Haematoma			

subjects affected / exposed occurrences (all) Hypertension subjects affected / exposed occurrences (all) Phlebitis subjects affected / exposed occurrences (all) Varicose Vein subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0 3 / 32 (9.38%) 3 0 / 32 (0.00%) 0 1 / 32 (3.13%) 1		
General disorders and administration site conditions Calcinosis subjects affected / exposed occurrences (all) Chest Discomfort subjects affected / exposed occurrences (all) Chest Pain subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Influenza Like Illness subjects affected / exposed occurrences (all) Oedema Peripheral subjects affected / exposed occurrences (all)	 0 / 32 (0.00%) 0 1 / 32 (3.13%) 1 2 / 32 (6.25%) 2 1 / 32 (3.13%) 1 0 / 32 (0.00%) 0 0 / 32 (0.00%) 0		
Immune system disorders Allergy To Arthropod Sting subjects affected / exposed occurrences (all)	 0 / 32 (0.00%) 0		
Reproductive system and breast disorders			

Breast Mass subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Fibrocystic Breast Disease subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		
Pelvic Pain subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Vulvovaginal Discomfort subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Oropharyngeal Pain subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		
Asthma subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Dyspnoea subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		
Dyspnoea Exertional subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		
Emphysema subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		
Haemoptysis subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		
Cough subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Psychiatric disorders			

Insomnia			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Alcoholism			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Dysthymic Disorder			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Stress			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Investigations			
Weight Increased			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Alanine Aminotransferase Increased			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Aspartate Aminotransferase Increased			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Blood 1,25-Dihydroxycholecalciferol Increased			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Blood Cholesterol Increased			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Blood Glucose Increased			

subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Blood Parathyroid Hormone Increased			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Blood Pressure Increased			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Blood Triglycerides Increased			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Carotid Bruit			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Glucose Urine Present			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
High Density Lipoprotein Decreased			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Weight Decreased			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
White Blood Cells Urine Positive			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Arthropod Sting			

subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Contusion				
subjects affected / exposed	3 / 32 (9.38%)			
occurrences (all)	7			
Epicondylitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Fall				
subjects affected / exposed	4 / 32 (12.50%)			
occurrences (all)	9			
Humerus Fracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Limb Injury				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Muscle Strain				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Wound				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Procedural Pain				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Radius Fracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Skull Fractured Base				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Spinal Compression Fracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Spinal Fracture				

subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Subdural Haematoma			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Thoracic Vertebral Fracture			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Tooth Fracture			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Wrist Fracture			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Laceration			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	3		
Ligament sprain			
subjects affected / exposed	4 / 32 (12.50%)		
occurrences (all)	4		
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Atrial Flutter			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Mitral Valve Prolapse			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		

Nervous system disorders			
Headache			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	4		
Memory Impairment			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Paraesthesia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	3		
Somnolence			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Tension Headache			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Trigeminal Neuralgia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Tinnitus			

subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Tympanosclerosis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Vertigo Positional			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Eye disorders			
Cataract			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Conjunctivitis Allergic			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Eye Pruritus			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Macular Degeneration			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	4		
Abdominal Pain			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	3		
Anal Fissure			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Constipation			

subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Diarrhoea				
subjects affected / exposed	2 / 32 (6.25%)			
occurrences (all)	2			
Dry Mouth				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Duodenal Ulcer				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	3 / 32 (9.38%)			
occurrences (all)	3			
Faecal Incontinence				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Flatulence				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Gastric Disorder				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Gastric Polyps				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Gastric Ulcer				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Gastrooesophageal Reflux Disease				
subjects affected / exposed	2 / 32 (6.25%)			
occurrences (all)	2			
Gingival Swelling				

subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Inguinal Hernia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Irritable Bowel Syndrome			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Mouth Ulceration			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Oesophagitis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Rectal Haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	4		
Dermatitis Atopic			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		

Ecchymosis				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Granuloma Annulare				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Hyperkeratosis				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Hypertrichosis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Lichen Planus				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Neurodermatitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Psoriasis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Rash				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Rash Erythematous				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Rash Papular				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Sebaceous Hyperplasia				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			

Skin Irritation			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Skin Lesion			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Thyroiditis Chronic			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Back Pain			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Bone Pain			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Bursitis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Costochondritis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Dupuytren's Contracture			

subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Foot Deformity				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Joint Stiffness				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Monarthritis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Muscle Contracture				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Muscle Spasms				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Muscular Weakness				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Musculoskeletal Chest Pain				
subjects affected / exposed	3 / 32 (9.38%)			
occurrences (all)	3			
Musculoskeletal Discomfort				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Musculoskeletal Pain				
subjects affected / exposed	4 / 32 (12.50%)			
occurrences (all)	4			
Musculoskeletal Stiffness				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Neck Pain				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Osteoarthritis				

subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Osteochondritis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Osteosclerosis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Pain In Extremity			
subjects affected / exposed	7 / 32 (21.88%)		
occurrences (all)	9		
Polyarthritis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Sacroiliitis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Synovial Cyst			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Tendonitis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Torticollis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Infections and infestations			
Bacterial Infection			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	5 / 32 (15.63%)		
occurrences (all)	5		

Cellulitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Chronic Sinusitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Cystitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Ear Infection				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Fungal Infection				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Furuncle				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Herpes Zoster				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	5 / 32 (15.63%)			
occurrences (all)	7			
Nasal Abscess				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	9 / 32 (28.13%)			
occurrences (all)	20			
Onychomycosis				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	2			

Oral Candidiasis				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Oral Herpes				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	2			
Otitis Media Acute				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			
Pharyngitis Streptococcal				
subjects affected / exposed	3 / 32 (9.38%)			
occurrences (all)	4			
Pneumonia				
subjects affected / exposed	3 / 32 (9.38%)			
occurrences (all)	4			
Pyoderma				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Respiratory Tract Infection				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Respiratory Tract Infection Viral				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 32 (0.00%)			
occurrences (all)	0			
Tooth Abscess				
subjects affected / exposed	1 / 32 (3.13%)			
occurrences (all)	1			

Tooth Infection subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2		
Urinary Tract Infection subjects affected / exposed occurrences (all)	7 / 32 (21.88%) 15		
Viral Infection subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Viral Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		
Eye infection subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2		
Metabolism and nutrition disorders Dyslipidaemia subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		
Hypercholesterolaemia subjects affected / exposed occurrences (all)	4 / 32 (12.50%) 4		
Hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 June 2006	AM1. The primary reason for this amendment was a revision to the protocol synopsis, in particular the data analysis section.
22 May 2007	EXT1/004-10. The primary reason for this amendment was to add a 12-month extension to the previous protocol (Protocol 004-01).
22 June 2007	AM2. The primary reason for this amendment was to add an 18-month interim analysis (Protocol 004-02).
03 April 2008	EXT1,AM1/004-11. The primary reason for this amendment was to add preliminary information on the predicted magnetic resonance imaging (MRI) findings suggestive of metaphyseal fibrosis in the ongoing growing monkey toxicology study at 10-fold preclinical/clinical margins, along with information on the absence of such findings at 12-fold preclinical/clinical margins in aged dogs.
03 June 2008	EXT2/004-20. The primary reason for this amendment was to add a 24-month extension to the previous protocol (Protocol 004-11).
11 December 2008	EXT2,AM1/004-21. The primary reason for this amendment was to add supplementary bone mineral density (BMD) scans at Visits 21 and 25 (Months 42 and 54) for additional efficacy measurements.
17 February 2010	EXT2,AM2/004-22. The primary reason for this amendment was to issue a revised definition of overdose for odanacatib to the following: Ingesting two or more tablets of study drug within a 5-day period.
25 May 2010	EXT3/004-30. The primary reason for this amendment was to add a 5-year extension to the previous protocol (Protocol 004-22).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported