A Dose-Ranging Study of MK-5442 in Postmenopausal Women With Osteoporosis (MK-5442-001)

This study has been terminated.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00960934

First received: August 17, 2009
Last updated: February 1, 2015
Last verified: February 2015
History of Changes

Purpose

The purpose of this study was to identify an appropriate dose of
MK-5442 that produced an osteoanabolic effect without causing hypercalcemia in postmenopausal women with osteoporosis.

Condition	Intervention	Phase
Osteoporosis	Drug: MK-5442 Drug: Placebo Dietary Supplement: Vitamin D3 Dietary Supplement: Calcium carbonate	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Phase IIb, Randomized, Placebo-Controlled, Dose-Ranging Study of MK-5442 in the Treatment of Postmenopausal Women With Osteoporosis

Resource links provided by NLM:

MedlinePlus related topics: Calcium Osteoporosis

Drug Information available for: Calcium Gluconate Calcium carbonate Vitamin D

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Least Squares (LS) Mean Percent Change From Baseline to Month 6 in Lumbar Spine Areal Bone Mineral Density (aBMD)
  [Time Frame: Baseline (BL) and Month 6] [Designated as safety issue: No]

  Dual Energy X-ray Absorptiometry (DXA) was used to assess and measure aBMD of the lumbar spine. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).

- Percentage of Participants With Total Serum Calcium Levels Outside the Pre-defined Limits of Change [Time Frame: Baseline through Month 6] [Designated as safety issue: Yes]

  Normal serum calcium level is 8-10 mg/dL (2-2.5 mmol/L) with some interlaboratory variation in the reference range, and hypercalcemia is defined as a serum calcium level greater than 10.5 mg/dL (>2.5 mmol/L). Based on these references, ≥10.6 mg/dL was predefined in this study as the cut-off for the normal limits of change. Participants with calcium levels ≥10.6 mg/dL were considered as having a "Tier 1" safety event.

- Percentage of Participants With Albumin-Corrected Calcium Levels Outside the Pre-defined Limits of Change [Time Frame: Baseline through Month 6] [Designated as safety issue: Yes]

  Albumin-Corrected Calcium = ([4 - plasma albumin in g/dL] × 0.8 + serum calcium). ≥10.6 mg/dL was predefined in this study as the cut-off for the normal limits of change. Participants with albumin-corrected calcium levels ≥10.6 mg/dL were considered as having a "Tier 1" safety event.

- Percentage of Participants With Kidney Stones [Time Frame: Baseline through Month 6] [Designated as safety issue: Yes]

  Evidence of kidney stone(s) was considered an event of interest and was prespecified as a "Tier 1" safety event.

- Percentage of Participants With Bone Neoplasms [Time Frame: Baseline through Month 6] [Designated as safety issue: Yes]

  Evidence of bone neoplasm(s) was considered an event of interest and was prespecified as a "Tier 1" safety event.

Secondary Outcome Measures:

- LS Mean Percent Change From Baseline to Month 6 in Total Hip aBMD [Time Frame: Baseline and Month 6]
  [Designated as safety issue: No]

  DXA was used to assess and measure aBMD of the total hip. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).

- LS Mean Percent Change From Baseline to Month 6 in Femoral Neck aBMD [Time Frame: Baseline and Month 6]
  [Designated as safety issue: No]

  DXA was used to assess and measure aBMD of the femoral neck. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).

- LS Mean Percent Change From Baseline to Month 6 in Trochanter aBMD [Time Frame: Baseline and Month 6]
  [Designated as safety issue: No]

  DXA was used to assess and measure aBMD of the trochanter. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).

- LS Mean Percent Change From Baseline to Month 6 in Total Body aBMD [Time Frame: Baseline and Month 6]
  [Designated as safety issue: No]

  DXA was used to assess and measure aBMD of the total body. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).

- LS Mean Percent Change From Baseline to Month 6 in Distal One-third Forearm Areal BMD [Time Frame: Baseline and Month 6]
  [Designated as safety issue: No]

  DXA was used to assess and measure aBMD of the distal 1/3 forearm. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).

- LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Hip [Time Frame: Baseline and Month 6]
  [Designated as safety issue: No]

  Quantitative computed tomography (QCT) technology was used to assess and measure bone mineral content volumetrically (ie, in grams of tissue per centimeter of tissue cubed).

- LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Lumbar Spine [Time Frame: Baseline and Month 6] [Designated as safety issue: No]

  Quantitative computed tomography (QCT) technology was used at baseline and periodically through out the study to assess and measure bone mineral content volumetrically (ie, in grams of tissue per centimeter of tissue cubed).

- LS Mean Percent Change From Baseline to Month 6 in the Ratio of Urinary N-Telopeptides of Type I Collagen to Creatinine (u-NTx/Cr) [Time Frame: Baseline and Month 6] [Designated as safety issue: No]

  The ratio of u-NTx to Cr is a biomarker for bone resorption. It is measured in the serum in units of nanomoles (nm) of bone collagen equivalents (BCE)/millimoles of creatinine (Cr).

- LS Mean Percent Change From Baseline to Month 6 in Serum C-Terminal Telopeptide Collagen I (s-CTx) [Time Frame: Baseline to Month 6] [Designated as safety issue: No]

  C-Terminal Telopeptide Collagen I is used as a serum-marker of bone resorption in the assessment of osteoporosis.

- LS Mean Percent Change From Baseline to Month 6 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP) [Time Frame: Baseline and Month 6] [Designated as safety issue: No]

  Bone Specific Alkaline Phosphatase is a biomarker of bone formation and is measured in units of microgram (µg)/liter (L).

- LS Mean Percent Change From Baseline to Month 6 in Serum Procollagen Type I N-Terminal Propeptide (P1NP) [Time Frame: Baseline to Month 6] [Designated as safety issue: No]

  Measurement of P1NP appears to be a sensitive marker of bone formation rate in the assessment of osteoporosis.

- LS Mean Percent Change From Baseline to Month 6 in Serum Osteocalcin [Time Frame: Baseline and Month 6] [Designated as safety issue: No]

  Serum osteocalcin is a biomarker of bone formation and is measured using units of nanograms (ng) / milliliter (mL).

Enrollment:	383
Study Start Date:	October 2009
Study Completion Date:	December 2010
Primary Completion Date:	December 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK-5442 2.5 mg Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.	Drug: MK-5442 MK-5442 2.5 mg, 5 mg, 7.5 mg, 10 mg, or 15 mg tablet once daily for at least 6 months. Drug: Placebo Dose-matched oral placebo to MK-5442 Dietary Supplement: Vitamin D3 Vitamin D3, two 400 IU tablets daily throughout the study. Dietary Supplement: Calcium carbonate Participants who had a calcium intake of less than 1200 mg/day at baseline received a daily 500 mg calcium supplement throughout the study.
Experimental: MK-5442 5 mg Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.	Drug: MK-5442 MK-5442 2.5 mg, 5 mg, 7.5 mg, 10 mg, or 15 mg tablet once daily for at least 6 months. Drug: Placebo Dose-matched oral placebo to MK-5442 Dietary Supplement: Vitamin D3 Vitamin D3, two 400 IU tablets daily throughout the study. Dietary Supplement: Calcium carbonate Participants who had a calcium intake of less than 1200 mg/day at baseline received a daily 500 mg calcium supplement throughout the study.

Experimental: MK-5442 7.5 mg Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.	Drug: MK-5442 MK-5442 2.5 mg, 5 mg, 7.5 mg, 10 mg, or 15 mg tablet once daily for at least 6 months. Drug: Placebo Dose-matched oral placebo to MK-5442 Dietary Supplement: Vitamin D3 Vitamin D3, two 400 IU tablets daily throughout the study. Dietary Supplement: Calcium carbonate Participants who had a calcium intake of less than 1200 mg/day at baseline received a daily 500 mg calcium supplement throughout the study.
Experimental: MK-5442 10 mg Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.	Drug: MK-5442 MK-5442 2.5 mg, 5 mg, 7.5 mg, 10 mg, or 15 mg tablet once daily for at least 6 months. Drug: Placebo Dose-matched oral placebo to MK-5442 Dietary Supplement: Vitamin D3 Vitamin D3, two 400 IU tablets daily throughout the study. Dietary Supplement: Calcium carbonate Participants who had a calcium intake of less than 1200 mg/day at baseline received a daily 500 mg calcium supplement throughout the study.
Experimental: MK-5442 15 mg Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.	Drug: MK-5442 MK-5442 2.5 mg, 5 mg, 7.5 mg, 10 mg, or 15 mg tablet once daily for at least 6 months. Drug: Placebo Dose-matched oral placebo to MK-5442 Dietary Supplement: Vitamin D3 Vitamin D3, two 400 IU tablets daily throughout the study. Dietary Supplement: Calcium carbonate Participants who had a calcium intake of less than 1200 mg/day at baseline received a daily 500 mg calcium supplement throughout the study.
Placebo Comparator: Placebo Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.	Drug: Placebo Dose-matched oral placebo to MK-5442 Dietary Supplement: Vitamin D3 Vitamin D3, two 400 IU tablets daily throughout the study. Dietary Supplement: Calcium carbonate Participants who had a calcium intake of less than 1200 mg/day at baseline received a daily 500 mg calcium supplement throughout the study.

Detailed Description:

Amendment 4 of the protocol changed the duration of the study from 2 years to 6 months.

Eligibility

Ages Eligible for Study:	45 Years to 85 Years
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Postmenopausal for at least 5 years
- No history of fragility fracture, unless participant is not willing to take marketed osteoporosis therapy or is not a candidate for marketed osteoporosis therapy

Agrees not to use medications for osteoporosis except medications associated with the study

- Areal bone mineral density (BMD) T-score <-2.5 at one or more of the following 4 BMD sites: total hip, femoral neck, trochanter, or lumbar spine and is ≥ -3.5 at all 4 BMD sites. Participants unwilling to take or ineligible for marketed osteoporosis therapy may have one or more areal BMD T-scores of < -3.5

Exclusion Criteria:

- Unable to undergo dual-energy X-ray absorptiometry (DXA) scan due to obesity (ie, weight >250 lbs)
- Use of oral bisphosphonates in the 6 months prior to study screening, for more than 3 months in the past 2 years, or lifetime use of more than 6 months
- Use of intravenous bisphosphonates, strontium, or growth hormone at any time
- Use of phenytoin or heparin within 2 weeks prior to Visit 1; use of raloxifene within 6 months prior to Visit 1
- Use of pioglitazone or rosiglitazone at study screening
- Use of estrogen ± progestin, in any form other than vaginal or topical application, for 6 months prior to Study Visit 1
- Prior total thyroidectomy
- Human immunodeficiency virus (HIV)- positive or acquired immune deficiency syndrome (AIDS)-related illness
- History of malignant cancer within 5 years of study screening, except for certain skin or cervical cancers
- History of Paget's disease and/or kidney stones
- An active user of any illicit drug
- History of or active alcohol abuse
- Participated in an investigational drug study within the past 30 days

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications:

Halse J, Greenspan S, Cosman F, Ellis G, Santora A, Leung A, Heyden N, Samanta S, Doleckyj S, Rosenberg E, Denker AE. A phase 2, randomized, placebo-controlled, dose-ranging study of the calcium-sensing receptor antagonist MK-5442 in the treatment of postmenopausal women with osteoporosis. J Clin Endocrinol Metab. 2014 Nov;99(11):E2207-15. doi: 10.1210/jc.2013-4009. Epub 2014 Aug 28.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00960934 History of Changes
Other Study ID Numbers:	5442-001 2009-012926-35
Study First Received:	August 17, 2009
Results First Received:	August 14, 2012
Last Updated:	February 1, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Osteoporosis
Postmenopausal
MK-5442

Additional relevant MeSH terms:

Osteoporosis	Calcium Carbonate
Bone Diseases	Antacids
Bone Diseases, Metabolic	Molecular Mechanisms of Pharmacological Action
Musculoskeletal Diseases	Pharmacologic Actions

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TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

A Dose-Ranging Study of MK-5442 in Postmenopausal Women With Osteoporosis (MK-5442-001)

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ClinicalTrials.gov Identifier:
NCT00960934

First received: August 17, 2009
Last updated: February 1, 2015
Last verified: February 2015
History of Changes

Results First Received: August 14, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Osteoporosis
Interventions:	Drug: MK-5442 Drug: Placebo Dietary Supplement: Vitamin D3 Dietary Supplement: Calcium carbonate

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
383 participants were randomized on study and 380 participants were treated on study.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Participant Flow: Overall Study

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
STARTED	64	63	64	64	64	64
Number Treated	64	62 [1]	64	64	63 [1]	63 [1]
COMPLETED	0	0	0	0	0	0
NOT COMPLETED	64	63	64	64	64	64
Adverse Event	2	3	3	2	4	3
Lack of Efficacy	1	0	0	0	0	0
Lost to Follow-up	0	1	0	0	0	0
Not Specified	2	1	5	4	2	2
Physician Decision	0	1	0	0	0	0
Progressive Disease	1	1	0	0	1	1
Protocol Violation	3	4	0	3	3	2
Withdrawal by Subject	5	6	4	5	5	7
Study Terminated by Sponsor	50	46	52	50	49	49

[1] 1 participant was randomized but not treated

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description

MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.
Total	Total of all reporting groups

Baseline Measures

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo	Total
Number of Participants [units: participants]	**64**	**63**	**64**	**64**	**64**	**64**	**383**
Age [units: years] Mean (Standard Deviation)	**66.7 (6.3)**	**67.3 (6.5)**	**67.4 (6.0)**	**67.8 (6.4)**	**66.5 (5.4)**	**67.6 (6.7)**	**67.2 (6.2)**
Gender [units: participants]							
Female	**64**	**63**	**64**	**64**	**64**	**64**	**383**
Male	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Outcome Measures

Hide All Outcome Measures

1. Primary: Least Squares (LS) Mean Percent Change From Baseline to Month 6 in Lumbar Spine Areal Bone Mineral Density (aBMD) [Time Frame: Baseline (BL) and Month 6]

Measure Type	Primary
Measure Title	Least Squares (LS) Mean Percent Change From Baseline to Month 6 in Lumbar Spine Areal Bone Mineral Density (aBMD)
Measure Description	Dual Energy X-ray Absorptiometry (DXA) was used to assess and measure aBMD of the lumbar spine. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).
Time Frame	Baseline (BL) and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Full Analysis Set (FAS); participants who received at least one dose of study treatment, had post-randomization data subsequent to at least one dose of study treatment, and who had baseline data.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Number of Participants Analyzed [units: participants]	**58**	**54**	**56**	**55**	**56**	**56**
Least Squares (LS) Mean Percent Change From Baseline to Month 6 in Lumbar Spine Areal Bone Mineral Density (aBMD) [units: percent change] Least Squares Mean (95% Confidence Interval)	**0.74 (-0.21 to 1.68)**	**1.50 (0.53 to 2.48)**	**0.92 (-0.02 to 1.87)**	**1.69 (0.73 to 2.64)**	**1.13 (0.18 to 2.08)**	**0.57 (-0.40 to 1.55)**

Statistical Analysis 1 for Least Squares (LS) Mean Percent Change From Baseline to Month 6 in Lumbar Spine Areal Bone Mineral Density (aBMD)

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.749
LS Mean Difference in Change From BL [4]	0.56
95% Confidence Interval	-1.04 to 2.16

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons for the areal BMD at lumbar spine endpoint were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.

[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Least Squares (LS) Mean Percent Change From Baseline to Month 6 in Lumbar Spine Areal Bone Mineral Density (aBMD)

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.333
LS Mean Difference in Change From BL [4]	1.12
95% Confidence Interval	-0.60 to 2.83

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons for the areal BMD at lumbar spine endpoint were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Least Squares (LS) Mean Percent Change From Baseline to Month 6 in Lumbar Spine Areal Bone Mineral Density (aBMD)

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.823
LS Mean Difference in Change From BL [4]	0.35
95% Confidence Interval	-1.14 to 1.84

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons for the areal BMD at lumbar spine endpoint were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Least Squares (LS) Mean Percent Change From Baseline to Month 6 in Lumbar Spine Areal Bone Mineral Density (aBMD)

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.457
LS Mean Difference in Change From BL [4]	0.93
95% Confidence Interval	-0.75 to 2.61

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons for the areal BMD at lumbar spine endpoint were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Least Squares (LS) Mean Percent Change From Baseline to Month 6 in Lumbar Spine Areal Bone Mineral Density (aBMD)

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.823
LS Mean Difference in Change From BL [4]	0.16
95% Confidence Interval	-1.17 to 1.50

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons for the areal BMD at lumbar spine endpoint were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

2. Primary: Percentage of Participants With Total Serum Calcium Levels Outside the Pre-defined Limits of Change [Time Frame: Baseline through Month 6]

Measure Type	Primary
Measure Title	Percentage of Participants With Total Serum Calcium Levels Outside the Pre-defined Limits of Change

Measure Description	Normal serum calcium level is 8-10 mg/dL (2-2.5 mmol/L) with some interlaboratory variation in the reference range, and hypercalcemia is defined as a serum calcium level greater than 10.5 mg/dL (>2.5 mmol/L). Based on these references, ≥10.6 mg/dL was predefined in this study as the cut-off for the normal limits of change. Participants with calcium levels ≥10.6 mg/dL were considered as having a "Tier 1" safety event.
Time Frame	Baseline through Month 6
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment. 3 randomized participants did not receive treatment and were not included in the APaT.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**64**	**62**	**64**	**64**	**63**	**63**
Percentage of Participants With Total Serum Calcium Levels Outside the Pre-defined Limits of Change [units: Percentage of participants]	**7.8**	**32.3**	**32.8**	**56.3**	**73.0**	**3.2**

Statistical Analysis 1 for Percentage of Participants With Total Serum Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	<0.001
Mean Difference (Final Values) [4]	69.8
95% Confidence Interval	56.5 to 80.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants With Total Serum Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	<0.001
Mean Difference (Final Values) [4]	53.1
95% Confidence Interval	39.6 to 65.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Percentage of Participants With Total Serum Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	<0.001
Mean Difference (Final Values) [4]	29.6
95% Confidence Interval	17.6 to 42.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the

	placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Percentage of Participants With Total Serum Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	<0.001
Mean Difference (Final Values) [4]	29.1
95% Confidence Interval	17.0 to 42.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Percentage of Participants With Total Serum Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	0.254
Mean Difference (Final Values) [4]	4.6
95% Confidence Interval	-4.1 to 14.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Primary: Percentage of Participants With Albumin-Corrected Calcium Levels Outside the Pre-defined Limits of Change [Time Frame: Baseline through Month 6]

Measure Type	Primary
Measure Title	Percentage of Participants With Albumin-Corrected Calcium Levels Outside the Pre-defined Limits of Change
Measure Description	Albumin-Corrected Calcium = ([4 - plasma albumin in g/dL] × 0.8 + serum calcium). ≥10.6 mg/dL was predefined in this study as the cut-off for the normal limits of change. Participants with albumin-corrected calcium levels ≥10.6 mg/dL were considered as having a "Tier 1" safety event.
Time Frame	Baseline through Month 6
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment. 3 randomized participants did not receive treatment and were not included in the APaT.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**64**	**62**	**64**	**64**	**63**	**63**

Percentage of Participants With Albumin-Corrected Calcium Levels Outside the Pre-defined Limits of Change [units: Percentage of participants]	**0.0**	**9.7**	**18.8**	**37.5**	**49.2**	**1.6**

Statistical Analysis 1 for Percentage of Participants With Albumin-Corrected Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	<0.001
Mean Difference (Final Values) [4]	47.6
95% Confidence Interval	34.9 to 60.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants With Albumin-Corrected Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	<0.001
Mean Difference (Final Values) [4]	35.9
95% Confidence Interval	24.1 to 48.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Percentage of Participants With Albumin-Corrected Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	0.001
Mean Difference (Final Values) [4]	17.2
95% Confidence Interval	7.7 to 28.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Percentage of Participants With Albumin-Corrected Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	0.050
Mean Difference (Final Values) [4]	8.1
95% Confidence Interval	-0.0 to 18.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Percentage of Participants With Albumin-Corrected Calcium Levels Outside the Pre-defined Limits of Change

Groups [1]	MK-5442 2.5 mg vs. Placebo

Method [2]	Miettinen and Nurminen Method
P Value [3]	0.313
Mean Difference (Final Values) [4]	-1.6
95% Confidence Interval	-8.5 to 4.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

4. Primary: Percentage of Participants With Kidney Stones [Time Frame: Baseline through Month 6]

Measure Type	Primary
Measure Title	Percentage of Participants With Kidney Stones
Measure Description	Evidence of kidney stone(s) was considered an event of interest and was prespecified as a "Tier 1" safety event.
Time Frame	Baseline through Month 6
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment. 3 randomized participants did not receive treatment and were not included in the APaT.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.

MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Number of Participants Analyzed [units: participants]	**64**	**62**	**64**	**64**	**63**	**63**
Percentage of Participants With Kidney Stones [units: Percentage of participants]	**1.6**	**1.6**	**0.0**	**0.0**	**0.0**	**0.0**

Statistical Analysis 1 for Percentage of Participants With Kidney Stones

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	>0.999
Mean Difference (Final Values) [4]	0.0
95% Confidence Interval	-5.8 to 5.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants With Kidney Stones

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	>0.999
Mean Difference (Final Values) [4]	0
95% Confidence Interval	-5.8 to 5.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Percentage of Participants With Kidney Stones

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	>0.999
Mean Difference (Final Values) [4]	0.0
95% Confidence Interval	-5.8 to 5.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Percentage of Participants With Kidney Stones

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	0.313
Mean Difference (Final Values) [4]	1.6
95% Confidence Interval	-4.2 to 8.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	

	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for Percentage of Participants With Kidney Stones

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Miettinen and Nurminen Method
P Value [3]	0.321
Mean Difference (Final Values) [4]	1.6
95% Confidence Interval	-4.3 to 8.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The Miettinen and Nurminen Method was used to estimate the treatment differences between the active dose group and the placebo group by comparing the percentage of participants in the active dose group with the event vs. the percentage of participants in the placebo group with the event. An associated p-value and 95% confidence interval were calculated for this difference.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

5. Primary: Percentage of Participants With Bone Neoplasms [Time Frame: Baseline through Month 6]

Measure Type	Primary
Measure Title	Percentage of Participants With Bone Neoplasms
Measure Description	Evidence of bone neoplasm(s) was considered an event of interest and was prespecified as a "Tier 1" safety event.
Time Frame	Baseline through Month 6
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All Participants as Treated (APaT) population; all randomized participants who received at least one dose of study treatment. 3 randomized participants did not receive treatment and were not included in the APaT.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Number of Participants Analyzed [units: participants]	**64**	**62**	**64**	**64**	**63**	**63**
Percentage of Participants With Bone Neoplasms [units: Percentage of participants]	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

No statistical analysis provided for Percentage of Participants With Bone Neoplasms

6. Secondary: LS Mean Percent Change From Baseline to Month 6 in Total Hip aBMD [Time Frame: Baseline and Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Total Hip aBMD
Measure Description	DXA was used to assess and measure aBMD of the total hip. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).
Time Frame	Baseline and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS); participants who received at least one dose of study treatment, had post-randomization data subsequent to at least one dose of study treatment, and who had baseline data.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of

	at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Number of Participants Analyzed [units: participants]	**58**	**54**	**56**	**55**	**56**	**56**
LS Mean Percent Change From Baseline to Month 6 in Total Hip aBMD [units: percent change] Least Squares Mean (95% Confidence Interval)	**-0.20 (-0.95 to 0.55)**	**-0.32 (-1.10 to 0.46)**	**0.32 (-0.43 to 1.07)**	**0.07 (-0.69 to 0.82)**	**0.33 (-0.43 to 1.08)**	**0.08 (-0.69 to 0.86)**

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Total Hip aBMD

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.959
LS Mean Difference in Change From BL [4]	0.24
95% Confidence Interval	-1.03 to 1.51

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Total Hip aBMD

Groups [1]	MK-5442 10 mg vs. Placebo

Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.971
LS Mean Difference in Change From BL [4]	-0.02
95% Confidence Interval	-1.08 to 1.04

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Total Hip aBMD

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.959
LS Mean Difference in Change From BL [4]	0.24
95% Confidence Interval	-0.95 to 1.42

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Total Hip aBMD

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.915
LS Mean Difference in Change From BL [4]	-0.41

95% Confidence Interval	-1.78 to 0.97

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Total Hip aBMD

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.959
LS Mean Difference in Change From BL [4]	-0.28
95% Confidence Interval	-1.60 to 1.04

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

7. Secondary: LS Mean Percent Change From Baseline to Month 6 in Femoral Neck aBMD [Time Frame: Baseline and Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Femoral Neck aBMD
Measure Description	DXA was used to assess and measure aBMD of the femoral neck. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).
Time Frame	Baseline and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS); participants who received at least one dose of study treatment, had post-randomization data subsequent to at least one dose of study treatment, and who had baseline data.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**58**	**54**	**56**	**55**	**56**	**56**
LS Mean Percent Change From Baseline to Month 6 in Femoral Neck aBMD [units: percent change] Least Squares Mean (95% Confidence Interval)	**1.23 (0.21 to 2.25)**	**-0.52 (-1.58 to 0.54)**	**0.12 (-0.89 to 1.14)**	**-0.20 (-1.23 to 0.83)**	**0.54 (-0.48 to 1.56)**	**-0.04 (-1.09 to 1.01)**

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Femoral Neck aBMD

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.849
LS Mean Difference in Change From BL [4]	0.58
95% Confidence Interval	-1.22 to 2.37

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Femoral Neck aBMD

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.964
LS Mean Difference in Change From BL [4]	-0.16
95% Confidence Interval	-1.79 to 1.47

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Femoral Neck aBMD

Groups [1]	MK-5442 7.5 mg
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.964
LS Mean Difference in Change From BL [4]	0.16
95% Confidence Interval	-1.27 to 1.59

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Femoral Neck aBMD

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.855
LS Mean Difference in Change From BL [4]	-0.48
95% Confidence Interval	-2.23 to 1.27

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Femoral Neck aBMD

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.287
LS Mean Difference in Change From BL [4]	1.27
95% Confidence Interval	-0.58 to 3.12

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

8. Secondary: LS Mean Percent Change From Baseline to Month 6 in Trochanter aBMD [Time Frame: Baseline and Month 6]

Measure Type	Secondary

Measure Title	LS Mean Percent Change From Baseline to Month 6 in Trochanter aBMD
Measure Description	DXA was used to assess and measure aBMD of the trochanter. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).
Time Frame	Baseline and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS); participants who received at least one dose of study treatment, had post-randomization data subsequent to at least one dose of study treatment, and who had baseline data.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**58**	**54**	**56**	**55**	**56**	**56**
LS Mean Percent Change From Baseline to Month 6 in Trochanter aBMD [units: percent change] Least Squares Mean (95% Confidence Interval)	**0.41 (-0.78 to 1.60)**	**0.95 (-0.29 to 2.19)**	**0.54 (-0.65 to 1.74)**	**0.49 (-0.72 to 1.70)**	**1.10 (-0.11 to 2.30)**	**0.49 (-0.74 to 1.73)**

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Trochanter aBMD

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.933
LS Mean Difference in Change From BL [4]	0.60
95% Confidence Interval	-1.56 to 2.77

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Trochanter aBMD

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.999
LS Mean Difference in Change From BL [4]	-0.01
95% Confidence Interval	-1.69 to 1.68

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Trochanter aBMD

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.999
LS Mean Difference in Change From BL [4]	0.05
95% Confidence Interval	-1.84 to 1.93

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Trochanter aBMD

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.959
LS Mean Difference in Change From BL [4]	0.45
95% Confidence Interval	-1.67 to 2.57

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Trochanter aBMD

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.999
LS Mean Difference in Change From BL [4]	-0.08
95% Confidence Interval	-2.10 to 1.94

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:

	No text entered.

9. Secondary: LS Mean Percent Change From Baseline to Month 6 in Total Body aBMD [Time Frame: Baseline and Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Total Body aBMD
Measure Description	DXA was used to assess and measure aBMD of the total body. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).
Time Frame	Baseline and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS); participants who received at least one dose of study treatment, had post-randomization data subsequent to at least one dose of study treatment, and who had baseline data.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**51**	**51**	**54**	**50**	**53**	**52**
LS Mean Percent Change From Baseline to Month 6 in Total Body aBMD [units: percent change] Least Squares Mean (95% Confidence Interval)	**0.43 (-0.11 to 0.97)**	**0.28 (-0.28 to 0.84)**	**0.80 (0.27 to 1.33)**	**0.21 (-0.35 to 0.76)**	**0.09 (-0.44 to 0.63)**	**0.27 (-0.29 to 0.82)**

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Total Body aBMD

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.976
LS Mean Difference in Change From BL [4]	-0.17
95% Confidence Interval	-1.12 to 0.77

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Total Body aBMD

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.982
LS Mean Difference in Change From BL [4]	-0.06
95% Confidence Interval	-0.93 to 0.80

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Total Body aBMD

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.489

LS Mean Difference in Change From BL [4]	0.53
95% Confidence Interval	-0.43 to 1.49

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Total Body aBMD

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.982
LS Mean Difference in Change From BL [4]	0.02
95% Confidence Interval	-0.75 to 0.78

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Total Body aBMD

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.976
LS Mean Difference in Change From BL [4]	0.16
95% Confidence Interval	-0.76 to 1.08

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

10. Secondary: LS Mean Percent Change From Baseline to Month 6 in Distal One-third Forearm Areal BMD [Time Frame: Baseline and Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Distal One-third Forearm Areal BMD
Measure Description	DXA was used to assess and measure aBMD of the distal 1/3 forearm. Areal BMD was measured as "areal" density using units of gram (gm) of tissue /centimeter of tissue squared (cm^2).
Time Frame	Baseline and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS); participants who received at least one dose of study treatment, had post-randomization data subsequent to at least one dose of study treatment, and who had baseline data.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Placebo**
Number of Participants Analyzed						

[units: participants]	51	51	55	49	53	52
LS Mean Percent Change From Baseline to Month 6 in Distal One-third Forearm Areal BMD [units: percent change] Least Squares Mean (95% Confidence Interval)	-0.47 (-1.42 to 0.48)	-0.32 (-1.30 to 0.65)	0.44 (-0.47 to 1.36)	-0.49 (-1.46 to 0.48)	-0.56 (-1.50 to 0.37)	-0.21 (-1.18 to 0.76)

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Distal One-third Forearm Areal BMD

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.961
LS Mean Difference in Change From BL [4]	-0.35
95% Confidence Interval	-2.00 to 1.31

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Distal One-third Forearm Areal BMD

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.961
LS Mean Difference in Change From BL [4]	-0.28
95% Confidence Interval	-1.90 to 1.34

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.

[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Distal One-third Forearm Areal BMD

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.778
LS Mean Difference in Change From BL [4]	0.66
95% Confidence Interval	-1.01 to 2.33

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Distal One-third Forearm Areal BMD

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.961
LS Mean Difference in Change From BL [4]	-0.11
95% Confidence Interval	-1.45 to 1.24

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Distal One-third Forearm Areal BMD

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.961
LS Mean Difference in Change From BL [4]	-0.25
95% Confidence Interval	-1.77 to 1.26

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

11. Secondary: LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Hip [Time Frame: Baseline and Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Hip
Measure Description	Quantitative computed tomography (QCT) technology was used to assess and measure bone mineral content volumetrically (ie, in grams of tissue per centimeter of tissue cubed).
Time Frame	Baseline and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS); participants who received at least one dose of study treatment, had post-randomization data subsequent to at least one dose of study treatment, and who had baseline data.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of

	at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Number of Participants Analyzed [units: participants]	**42**	**43**	**46**	**39**	**41**	**50**
LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Hip [units: percent change] Least Squares Mean (95% Confidence Interval)	**-0.41 (-1.44 to 0.62)**	**-0.34 (-1.43 to 0.75)**	**-0.89 (-1.90 to 0.13)**	**-0.88 (-1.97 to 0.22)**	**-0.80 (-1.87 to 0.26)**	**-0.37 (-1.37 to 0.63)**

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Hip

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.901
LS Mean Difference in Change From BL [4]	-0.43
95% Confidence Interval	-2.03 to 1.17

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Hip

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.901
LS Mean Difference in Change From BL [4]	-0.51
95% Confidence Interval	-2.18 to 1.17

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Hip

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.901
LS Mean Difference in Change From BL [4]	-0.52
95% Confidence Interval	-2.17 to 1.13

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Hip

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.997
LS Mean Difference in Change From BL [4]	0.03
95% Confidence Interval	-1.29 to 1.35

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Hip

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.997
LS Mean Difference in Change From BL [4]	-0.04
95% Confidence Interval	-1.51 to 1.43

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

12. Secondary: LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Lumbar Spine [Time Frame: Baseline and Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Lumbar Spine
Measure Description	Quantitative computed tomography (QCT) technology was used at baseline and periodically through out the study to assess and measure bone mineral content volumetrically (ie, in grams of tissue per centimeter of tissue cubed).
Time Frame	Baseline and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS); participants who received at least one dose of study treatment, had post-randomization data subsequent to at least one dose of study treatment, and who had baseline data.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Number of Participants Analyzed [units: participants]	**43**	**43**	**44**	**39**	**40**	**50**
LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Lumbar Spine [units: percent change] Least Squares Mean (95% Confidence Interval)	**1.94 (0.13 to 3.75)**	**0.94 (-0.97 to 2.85)**	**1.83 (0.02 to 3.64)**	**3.35 (1.43 to 5.27)**	**1.06 (-0.83 to 2.96)**	**1.43 (-0.33 to 3.19)**

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Lumbar Spine

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.979
LS Mean Difference in Change From BL [4]	-0.37
95% Confidence Interval	-2.73 to 1.99

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Lumbar Spine

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.363
LS Mean Difference in Change From BL [4]	1.92
95% Confidence Interval	-1.10 to 4.95

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Lumbar Spine

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.979
LS Mean Difference in Change From BL [4]	0.40
95% Confidence Interval	-2.18 to 2.98

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Lumbar Spine

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.979

LS Mean Difference in Change From BL [4]	-0.49
95% Confidence Interval	-3.27 to 2.30

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Trabecular Volumetric BMD of the Lumbar Spine

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.979
LS Mean Difference in Change From BL [4]	0.51
95% Confidence Interval	-2.34 to 3.37

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

13. Secondary: LS Mean Percent Change From Baseline to Month 6 in the Ratio of Urinary N-Telopeptides of Type I Collagen to Creatinine (u-NTx/Cr) [Time Frame: Baseline and Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in the Ratio of Urinary N-Telopeptides of Type I Collagen to Creatinine (u-NTx/Cr)
Measure Description	The ratio of u-NTx to Cr is a biomarker for bone resorption. It is measured in the serum in units of nanomoles (nm) of bone collagen equivalents (BCE)/millimoles of creatinine (Cr).
Time Frame	Baseline and Month 6

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol population; defined as the subset of the APaT population that excluded participants based on critical protocol violations.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**50**	**51**	**53**	**51**	**52**	**53**
LS Mean Percent Change From Baseline to Month 6 in the Ratio of Urinary N-Telopeptides of Type I Collagen to Creatinine (u-NTx/Cr) [units: percent change] Least Squares Mean (95% Confidence Interval)	**-12.18 (-21.23 to -2.10)**	**-9.46 (-18.87 to 1.03)**	**-20.73 (-28.79 to -11.76)**	**-7.82 (-17.33 to 2.78)**	**1.87 (-8.53 to 13.45)**	**-17.90 (-26.15 to -8.73)**

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in the Ratio of Urinary N-Telopeptides of Type I Collagen to Creatinine (u-NTx/Cr)

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.020
LS Mean Difference in Change From BL [4]	19.77
95% Confidence Interval	2.26 to 37.46

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in the Ratio of Urinary N-Telopeptides of Type I Collagen to Creatinine (u-NTx/Cr)

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.357
LS Mean Difference in Change From BL [4]	10.08
95% Confidence Interval	-6.16 to 26.41

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in the Ratio of Urinary N-Telopeptides of Type I Collagen to Creatinine (u-NTx/Cr)

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.642
LS Mean Difference in Change From BL [4]	-2.83
95% Confidence Interval	-14.81 to 9.14

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in the Ratio of Urinary N-Telopeptides of Type I Collagen to Creatinine (u-NTx/Cr)

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.434
LS Mean Difference in Change From BL [4]	8.44
95% Confidence Interval	-7.09 to 24.04

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in the Ratio of Urinary N-Telopeptides of Type I Collagen to Creatinine (u-NTx/Cr)

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.579
LS Mean Difference in Change From BL [4]	5.72
95% Confidence Interval	-8.62 to 20.10

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time

	point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

14. Secondary: LS Mean Percent Change From Baseline to Month 6 in Serum C-Terminal Telopeptide Collagen I (s-CTx) [Time Frame: Baseline to Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Serum C-Terminal Telopeptide Collagen I (s-CTx)
Measure Description	C-Terminal Telopeptide Collagen I is used as a serum-marker of bone resorption in the assessment of osteoporosis.
Time Frame	Baseline to Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol population; defined as the subset of the APaT population that excluded participants based on critical protocol violations.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**49**	**51**	**54**	**52**	**52**	**52**
LS Mean Percent Change From Baseline to Month 6 in Serum C-Terminal Telopeptide Collagen I (s-CTx) [units: percent change] Least Squares Mean (95%	**-15.39 (-23.80 to -6.05)**	**-5.87 (-15.32 to 4.63)**	**-4.93 (-14.23 to 5.39)**	**5.68 (-4.77 to 17.27)**	**19.37 (7.60 to 32.43)**	**-14.89 (-23.24 to -5.64)**

Confidence Interval)						

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Serum C-Terminal Telopeptide Collagen I (s-CTx)

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.001
LS Mean Difference in Change From BL [4]	34.26
95% Confidence Interval	15.27 to 53.56

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Serum C-Terminal Telopeptide Collagen I (s-CTx)

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis
P Value [3]	0.014
LS Mean Difference in Change From BL [4]	20.57
95% Confidence Interval	3.28 to 38.02

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Serum C-Terminal Telopeptide Collagen I (s-CTx)

Groups [1]	MK-5442 7.5 mg vs. Placebo

Method [2]	Longitudinal Data Analysis
P Value [3]	0.307
LS Mean Difference in Change From BL [4]	9.97
95% Confidence Interval	-5.69 to 25.70

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Serum C-Terminal Telopeptide Collagen I (s-CTx)

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis
P Value [3]	0.307
LS Mean Difference in Change From BL [4]	9.02
95% Confidence Interval	-5.85 to 23.95

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Serum C-Terminal Telopeptide Collagen I (s-CTx)

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis
P Value [3]	0.937
LS Mean Difference in Change From BL [4]	-0.50

95% Confidence Interval	-12.92 to 11.92

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

15. Secondary: LS Mean Percent Change From Baseline to Month 6 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP) [Time Frame: Baseline and Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)
Measure Description	Bone Specific Alkaline Phosphatase is a biomarker of bone formation and is measured in units of microgram (µg)/liter (L).
Time Frame	Baseline and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol population; defined as the subset of the APaT population that excluded participants based on critical protocol violations.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Number of Participants Analyzed [units: participants]	49	51	54	52	52	52
LS Mean Percent Change From Baseline to Month 6 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP) [units: percent change] Least Squares Mean (95% Confidence Interval)	-0.60 (-6.87 to 6.10)	0.26 (-6.17 to 7.13)	4.39 (-2.13 to 11.35)	17.33 (9.93 to 25.22)	13.13 (6.02 to 20.72)	-6.05 (-11.92 to 0.20)

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
LS Mean Difference in Change From BL [4]	19.19
95% Confidence Interval	7.42 to 31.02

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
LS Mean Difference in Change From BL [4]	23.38
95% Confidence Interval	11.02 to 35.82

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.061
LS Mean Difference in Change From BL [4]	10.45
95% Confidence Interval	-0.37 to 21.30

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.283
LS Mean Difference in Change From BL [4]	6.31
95% Confidence Interval	-3.81 to 16.45

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Serum Bone-Specific Alkaline Phosphatase (s-BSAP)

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.283
LS Mean Difference in Change From BL [4]	5.46
95% Confidence Interval	-3.39 to 14.31

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

16. Secondary: LS Mean Percent Change From Baseline to Month 6 in Serum Procollagen Type I N-Terminal Propeptide (P1NP) [Time Frame: Baseline to Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Serum Procollagen Type I N-Terminal Propeptide (P1NP)
Measure Description	Measurement of P1NP appears to be a sensitive marker of bone formation rate in the assessment of osteoporosis.
Time Frame	Baseline to Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The 'Per Protocol' population was used for this analysis. The Per-Protocol population was defined as a subset population that excluded participants based on critical protocol violations.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of

	at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Number of Participants Analyzed [units: participants]	**49**	**51**	**54**	**52**	**52**	**52**
LS Mean Percent Change From Baseline to Month 6 in Serum Procollagen Type I N-Terminal Propeptide (P1NP) [units: percent change] Least Squares Mean (95% Confidence Interval)	**-9.97 (-18.46 to -0.59)**	**-9.76 (-18.36 to -0.26)**	**2.33 (-7.16 to 12.78)**	**21.30 (9.91 to 33.88)**	**38.41 (25.45 to 52.71)**	**-18.36 (-25.96 to -9.97)**

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Serum Procollagen Type I N-Terminal Propeptide (P1NP)

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis
P Value [3]	<.001
LS Mean Difference in Change From BL [4]	56.77
95% Confidence Interval	37.62 to 76.35

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Serum Procollagen Type I N-Terminal Propeptide (P1NP)

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis
P Value [3]	<.001

LS Mean Difference in Change From BL [4]	39.66
95% Confidence Interval	22.44 to 57.17

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Serum Procollagen Type I N-Terminal Propeptide (P1NP)

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis
P Value [3]	0.003
LS Mean Difference in Change From BL [4]	20.68
95% Confidence Interval	5.72 to 35.78

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Serum Procollagen Type I N-Terminal Propeptide (P1NP)

Groups [1]	MK-5442 5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis
P Value [3]	0.265
LS Mean Difference in Change From BL [4]	8.59
95% Confidence Interval	-4.81 to 22.05

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Serum Procollagen Type I N-Terminal Propeptide (P1NP)

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis
P Value [3]	0.265
LS Mean Difference in Change From BL [4]	8.39
95% Confidence Interval	-3.40 to 20.21

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

17. Secondary: LS Mean Percent Change From Baseline to Month 6 in Serum Osteocalcin [Time Frame: Baseline and Month 6]

Measure Type	Secondary
Measure Title	LS Mean Percent Change From Baseline to Month 6 in Serum Osteocalcin
Measure Description	Serum osteocalcin is a biomarker of bone formation and is measured using units of nanograms (ng) / milliliter (mL).
Time Frame	Baseline and Month 6
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Per Protocol population; defined as the subset of the APaT population that excluded participants based on critical protocol violations.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Measured Values

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Number of Participants Analyzed [units: participants]	**49**	**51**	**54**	**52**	**52**	**52**
LS Mean Percent Change From Baseline to Month 6 in Serum Osteocalcin [units: percent change] Least Squares Mean (95% Confidence Interval)	**-11.61 (-18.19 to -4.50)**	**-2.75 (-10.10 to 5.19)**	**9.18 (1.15 to 17.86)**	**25.79 (16.45 to 35.88)**	**37.43 (27.24 to 48.42)**	**-15.62 (-21.83 to -8.92)**

Statistical Analysis 1 for LS Mean Percent Change From Baseline to Month 6 in Serum Osteocalcin

Groups [1]	MK-5442 15 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
LS Mean Difference in Change From BL [4]	53.05
95% Confidence Interval	37.83 to 68.53

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:

	No text entered.

Statistical Analysis 2 for LS Mean Percent Change From Baseline to Month 6 in Serum Osteocalcin

Groups [1]	MK-5442 10 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
LS Mean Difference in Change From BL [4]	41.41
95% Confidence Interval	27.36 to 55.65

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for LS Mean Percent Change From Baseline to Month 6 in Serum Osteocalcin

Groups [1]	MK-5442 7.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	<0.001
LS Mean Difference in Change From BL [4]	24.81
95% Confidence Interval	12.39 to 37.33

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for LS Mean Percent Change From Baseline to Month 6 in Serum Osteocalcin

Groups [1]	MK-5442 5 mg vs. Placebo

Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.020
LS Mean Difference in Change From BL [4]	12.87
95% Confidence Interval	1.73 to 24.06

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 5 for LS Mean Percent Change From Baseline to Month 6 in Serum Osteocalcin

Groups [1]	MK-5442 2.5 mg vs. Placebo
Method [2]	Longitudinal Data Analysis Model
P Value [3]	0.397
LS Mean Difference in Change From BL [4]	4.02
95% Confidence Interval	-5.31 to 13.36

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The Type-I error rate over the multiple treatment dose comparisons were controlled by step-down Dunnett's test at the primary time point of Month 6, at an alpha level of 0.05, two-sided.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From October 2, 2009 to December 21, 2010, with an in-house data-cut date of February 10, 2011
Additional Description	All Participants as Treated (APaT) Population. Three participants were randomized but not treated, and thus are not

	included in the adverse event table calculations (one participant was randomized to 5 mg MK-5442; one participant was randomized to 15 mg MK-5442 and one participant was randomized to Placebo.

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Serious Adverse Events

	MK-5442 2.5 mg	MK-5442 5 mg	MK-5442 7.5 mg	MK-5442 10 mg	MK-5442 15 mg	Placebo
Total, serious adverse events						
# participants affected / at risk	**3/64 (4.69%)**	**0/62 (0.00%)**	**4/64 (6.25%)**	**5/64 (7.81%)**	**4/63 (6.35%)**	**3/63 (4.76%)**
Cardiac disorders						
Angina pectoris aggravated † 1						
# participants affected / at risk	**1/64 (1.56%)**	**0/62 (0.00%)**	**0/64 (0.00%)**	**0/64 (0.00%)**	**0/63 (0.00%)**	**0/63 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**
Atrial flutter † 1						
# participants affected / at risk	**0/64 (0.00%)**	**0/62 (0.00%)**	**0/64 (0.00%)**	**1/64 (1.56%)**	**0/63 (0.00%)**	**0/63 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**
Ischaemic heart disease † 1						
# participants affected / at risk	**0/64 (0.00%)**	**0/62 (0.00%)**	**0/64 (0.00%)**	**1/64 (1.56%)**	**0/63 (0.00%)**	**0/63 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**
Paroxysmal atrial fibrillation † 2						
# participants affected / at risk	**0/64 (0.00%)**	**0/62 (0.00%)**	**0/64 (0.00%)**	**1/64 (1.56%)**	**0/63 (0.00%)**	**0/63 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**	**0**
Supraventricular tachycardia † 1						
# participants affected / at risk	**0/64 (0.00%)**	**0/62 (0.00%)**	**0/64 (0.00%)**	**1/64 (1.56%)**	**0/63 (0.00%)**	**0/63 (0.00%)**

# events	0	0	0	1	0	0
Gastrointestinal disorders						
External haemorrhoids † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	1/64 (1.56%)	0/64 (0.00%)	0/63 (0.00%)	0/63 (0.00%)
# events	0	0	1	0	0	0
Peptic ulcer † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	1/63 (1.59%)	0/63 (0.00%)
# events	0	0	0	0	1	0
Hepatobiliary disorders						
Cholelithiasis † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	1/63 (1.59%)	0/63 (0.00%)
# events	0	0	0	0	1	0
Infections and infestations						
Cellulitis of leg † 1						
# participants affected / at risk	1/64 (1.56%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	0/63 (0.00%)	0/63 (0.00%)
# events	1	0	0	0	0	0
Pyelonephritis acute † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	1/64 (1.56%)	0/64 (0.00%)	0/63 (0.00%)	0/63 (0.00%)
# events	0	0	1	0	0	0
Injury, poisoning and procedural complications						
Ankle fracture † 1						
# participants affected / at risk	1/64 (1.56%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	0/63 (0.00%)	0/63 (0.00%)
# events	1	0	0	0	0	0
Burn † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	1/63 (1.59%)	0/63 (0.00%)
# events	0	0	0	0	1	0
Coronary stent stenosis † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	0/63 (0.00%)	1/63 (1.59%)
# events	0	0	0	0	0	1
Musculoskeletal and connective tissue disorders						
Fracture malunion † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	0/63 (0.00%)	1/63 (1.59%)

# events	0	0	0	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Breast cancer † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	1/64 (1.56%)	0/64 (0.00%)	0/63 (0.00%)	0/63 (0.00%)
# events	0	0	1	0	0	0
Breast cancer stage II † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	1/64 (1.56%)	0/63 (0.00%)	0/63 (0.00%)
# events	0	0	0	1	0	0
Gallbladder carcinoma † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	1/63 (1.59%)	0/63 (0.00%)
# events	0	0	0	0	1	0
Nervous system disorders						
Sciatica † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	0/63 (0.00%)	1/63 (1.59%)
# events	0	0	0	0	0	1
Stroke † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	1/64 (1.56%)	0/63 (0.00%)	0/63 (0.00%)
# events	0	0	0	1	0	0
Reproductive system and breast disorders						
Breast cyst † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	1/64 (1.56%)	0/64 (0.00%)	0/63 (0.00%)	0/63 (0.00%)
# events	0	0	1	0	0	0
Ovarian cyst † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	0/64 (0.00%)	1/63 (1.59%)	0/63 (0.00%)
# events	0	0	0	0	1	0
Respiratory, thoracic and mediastinal disorders						
COPD exacerbation † 1						
# participants affected / at risk	0/64 (0.00%)	0/62 (0.00%)	0/64 (0.00%)	1/64 (1.56%)	0/63 (0.00%)	0/63 (0.00%)
# events	0	0	0	1	0	0
Vascular disorders						
Postural hypotension † 1						

# participants affected / at risk	**0/64 (0.00%)**	**0/62 (0.00%)**	**1/64 (1.56%)**	**0/64 (0.00%)**	**0/63 (0.00%)**	**0/63 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (14.0)
2 Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	From October 2, 2009 to December 21, 2010, with an in-house data-cut date of February 10, 2011
Additional Description	All Participants as Treated (APaT) Population. Three participants were randomized but not treated, and thus are not included in the adverse event table calculations (one participant was randomized to 5 mg MK-5442; one participant was randomized to 15 mg MK-5442 and one participant was randomized to Placebo.

Frequency Threshold

Threshold above which other adverse events are reported	0.05%

Reporting Groups

	Description
MK-5442 2.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 2.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 7.5 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 7.5 mg of MK-5442 for a duration of at least 6 months.
MK-5442 10 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 10 mg of MK-5442 for a duration of at least 6 months.
MK-5442 15 mg	Following a 2-week open-label placebo run-in, participants received a daily oral dose of 15 mg of MK-5442 for a duration of at least 6 months.
Placebo	Following a 2-week open-label placebo run-in, participants received a daily oral dose of placebo dose-matched to MK-5442 for a duration of at least 6 months.

Other Adverse Events

	MK-5442 2.5 mg	**MK-5442 5 mg**	**MK-5442 7.5 mg**	**MK-5442 10 mg**	**MK-5442 15 mg**	**Placebo**
Total, other (not including serious) adverse events						
# participants affected / at risk	**18/64 (28.13%)**	**24/62 (38.71%)**	**15/64 (23.44%)**	**28/64 (43.75%)**	**18/63 (28.57%)**	**26/63 (41.27%)**
Gastrointestinal disorders						
Constipation † 1						
# participants affected / at risk	**2/64 (3.13%)**	**4/62 (6.45%)**	**4/64 (6.25%)**	**7/64 (10.94%)**	**5/63 (7.94%)**	**4/63 (6.35%)**
# events	**2**	**4**	**4**	**7**	**5**	**6**

Nausea † 1						
# participants affected / at risk	**2/64 (3.13%)**	**0/62 (0.00%)**	**2/64 (3.13%)**	**2/64 (3.13%)**	**2/63 (3.17%)**	**5/63 (7.94%)**
# events	**2**	**0**	**3**	**2**	**2**	**5**
General disorders						
Tiredness † 1						
# participants affected / at risk	**0/64 (0.00%)**	**1/62 (1.61%)**	**0/64 (0.00%)**	**1/64 (1.56%)**	**0/63 (0.00%)**	**4/63 (6.35%)**
# events	**0**	**1**	**0**	**1**	**0**	**5**
Infections and infestations						
Chest Infection † 1						
# participants affected / at risk	**2/64 (3.13%)**	**1/62 (1.61%)**	**1/64 (1.56%)**	**4/64 (6.25%)**	**2/63 (3.17%)**	**1/63 (1.59%)**
# events	**2**	**2**	**1**	**4**	**2**	**1**
Common Cold † 1						
# participants affected / at risk	**4/64 (6.25%)**	**3/62 (4.84%)**	**3/64 (4.69%)**	**5/64 (7.81%)**	**1/63 (1.59%)**	**3/63 (4.76%)**
# events	**4**	**3**	**3**	**5**	**1**	**5**
Upper Respiratory Tract Infection † 1						
# participants affected / at risk	**3/64 (4.69%)**	**2/62 (3.23%)**	**2/64 (3.13%)**	**2/64 (3.13%)**	**3/63 (4.76%)**	**6/63 (9.52%)**
# events	**3**	**2**	**2**	**2**	**3**	**7**
Urinary Tract Infection † 1						
# participants affected / at risk	**5/64 (7.81%)**	**5/62 (8.06%)**	**2/64 (3.13%)**	**10/64 (15.63%)**	**3/63 (4.76%)**	**6/63 (9.52%)**
# events	**8**	**6**	**3**	**12**	**5**	**6**
Musculoskeletal and connective tissue disorders						
Pain in Hip † 1						
# participants affected / at risk	**0/64 (0.00%)**	**4/62 (6.45%)**	**1/64 (1.56%)**	**0/64 (0.00%)**	**3/63 (4.76%)**	**1/63 (1.59%)**
# events	**0**	**5**	**1**	**0**	**3**	**1**
Nervous system disorders						
Headache † 1						
# participants affected / at risk	**5/64 (7.81%)**	**6/62 (9.68%)**	**2/64 (3.13%)**	**4/64 (6.25%)**	**5/63 (7.94%)**	**5/63 (7.94%)**
# events	**5**	**6**	**3**	**4**	**5**	**6**
Respiratory, thoracic and mediastinal disorders						
Cough † 1						
# participants affected / at risk	**2/64 (3.13%)**	**3/62 (4.84%)**	**1/64 (1.56%)**	**4/64 (6.25%)**	**2/63 (3.17%)**	**0/63 (0.00%)**
# events	**2**	**3**	**1**	**4**	**2**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (14.0)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** Subsequent to the multicenter publication, or 24 months after completion of the study, whichever comes first, an investigator and/or his/her colleagues may publish the results of the study associated with their study site independently.

Results Point of Contact:

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Publications of Results:

Halse J, Greenspan S, Cosman F, Ellis G, Santora A, Leung A, Heyden N, Samanta S, Doleckyj S, Rosenberg E, Denker AE. A phase 2, randomized, placebo-controlled, dose-ranging study of the calcium-sensing receptor antagonist MK-5442 in the treatment of postmenopausal women with osteoporosis. J Clin Endocrinol Metab. 2014 Nov;99(11):E2207-15. doi: 10.1210/jc.2013-4009. Epub 2014 Aug 28.

Responsible Party:	Merck Sharp & Dohme Corp.
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Health Authority:	United States: Food and Drug Administration

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