An Observational Follow-Up Study for: A Phase III Randomized, Placebo-Controlled Clinical Trial to Assess the Safety and Efficacy of Odanacatib (MK-0822) to Reduce the Risk of Fracture in Osteoporotic Postmenopausal Women Treated With Vitamin D and Calcium (Protocol 018) (MK-0822-083)

SECONDARY IDENTIFICATION NUMBER

MK0822-083, CDRR-2013-11270

SCIENTIFIC TITLE

An Observational Follow-Up Study for: A Phase III Randomized, Placebo-Controlled Clinical Trial to Assess the Safety and Efficacy of Odanacatib (MK-0822) to Reduce the Risk of Fracture in Osteoporotic Postmenopausal Women Treated With Vitamin D and Calcium (Protocol 018) (MK-0822-083)

PROJECT DESCRIPTION

This is an observational follow-up study to Protocol 018 (A Phase III Randomized, Placebo-Controlled Clinical Trial to Assess the Safety and Efficacy of Odanacatib (MK-0822) to Reduce the Risk of Fracture in Osteoporotic Postmenopausal Women Treated With Vitamin D and Calcium [1]). The objective of this study is to collect additional information regarding specific types of adverse events in subjects who have completed the base study, or have discontinued study drug (during the base or 1st extension) and have not completed follow-up to the end of the 5-year double-blind treatment period of Protocol 018 base study and its 1st extension. This study will enroll the following groups of subjects: those who (1) discontinued from Protocol 018 base study prior to study close-out, (2) completed the base study of Protocol 018 and did not continue into the 1st extension of Protocol 018, (3) discontinued the 1st extension study (Protocol 018-10/Protocol 018-05) prior to reaching the open-label portion of the study, or (4) discontinued the amended 1st extension study (Protocol 018-06) prior to reaching the open-label period of the study and did not consent to continue follow-up clinic visits and study procedures. The types of adverse events for which we will collect additional information in the current study include (1) deaths, (2) serious adverse events (SAEs), (3) adverse events that would have required adjudication in Protocol 018 (NOTE: Not all fractures will be adjudicated as part of this study; only delayed fracture union and atypical femoral shaft fractures are to be adjudicated.), and (4) skin events of clinical interest (ECI). The information to be collected includes additional data regarding these types of adverse events that were reported during the subject's participation in Protocol 018 or its 1st extension, and any new occurrence of such adverse events after the subject discontinued or completed Protocol 018, or after the subject discontinued the 1st extension of Protocol 018.

PROJECT DURATION

Start Date	Duration in Months	Target Completion Date	Actual Completion Date
2014-03-03	37	2017-04-03	2017-04-10

PROJECT STATUS

Completed

REASON FOR PROJECT PENDING/SUSPENSION/TERMINATION

Unspecified

IMPLEMENTING AGENCY (PRIMARY SPONSOR)

Institution	Classification	Region	LTO #
Merck Sharp & Dohme (I.A.) LLC	Private Business	NCR	CDRR-NCR-S-16

COOPERATING AGENCY (SECONDARY SPONSOR)

Institution	Classification	Region	LTO #
No records Found.			

FUNDING AGENCY (SOURCES OF MONETARY OR MATERIAL SUPPORT)

Institution	Amount	Region
Merck Sharp & Dohme (I.A.) LLC	N/A	NCR

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IMPLEMENTING AGENCY (PRIMARY SPONSOR)

Name	Expertise	Affiliation
Agustin Miguel Morales, MD	Orthopedics	Cebu Orthopaedic Institute
Julie T. Li Yu, MD	Rheumatology	University of Santo Tomas Hospital
Perry P. Tan, MD	Rheumatology	Jose R. Reyes Memorial Medical Center
Genaro Wilfred Francisco Asis, MD	Orthopedics	Philippine Orthopedic Institute, Inc.

HEALTH CONDITION(S) OR PROBLEM(S) STUDIED

Osteoporosis

PRIMARY OUTCOMES

To collect and assess safety information for the double-blinded treatment period ending 5 years post-randomization regarding deaths, SAEs, adverse events requiring adjudication, and skin ECIs in subjects who were randomized and took at least one dose of blinded study medication, then discontinued from study drug but have not completed follow-up through the 5-year blinded treatment period of Protocol 018 and its 1st extension. These data will be analyzed together with data from subjects who have completed 5 years of blinded study medication.

KEY SECONDARY OUTCOMES

Not applicable

RECRUITMENT STATUS

Completed

COUNTRIES OF RECRUITMENT

Japan, Latvia, Lithuania, Mexico, New Zealand, Norway, Peru, Philippines, Poland, Romania, Russia, Serbia, South Africa, South Korea, Spain, Switzerland, Taiwan, Ukraine, United Kingdom, United States

RESEARCH CLASSIFICATION

Clinical Trial

FDA DOCUMENT TRACKING NUMBER

Unspecified

FDA/ERC APPROVAL DATE

2013-09-24

AMENDMENT APPROVAL DATE/REASONS

Classification	Approval Date	Reason
No records Found.		

KEY INCLUSION AND EXLUSION CRITERIA (CT)

Subject Inclusion Criteria: In order to be eligible for participation in this trial, the subject must: 1. Have been randomized into Protocol 018 2. Have taken at least 1 dose of blinded study medication 3. Have discontinued from Protocol 018 base study prior to study close-out OR have completed the base study of Protocol 018 and did not continue into the 1st extension of Protocol 018 OR have discontinued the 1st extension study (Protocol 018-10/Protocol 018-05) prior to reaching the open-label portion of the study OR have discontinued the amended 1st extension study (Protocol 018-06) prior to reaching the open-label period of the study and did not consent to continue follow-up clinic visits and study procedures. Subject Exclusion Criteria: The subject must be excluded from participating in the trial if the subject: 1. Had her Protocol 018 treatment group assignment unblinded, prior to the open-label period 2. Has discontinued treatment after she entered into the open-label period

STUDY TYPE

Observational

INTERVENTION NAME

Unspecified

INTERVENTION DESCRIPTION

Unspecified

METHOD OF ALLOCATION

Non-randomized

MASKING / BLINDING

Not Applicable

MASKING DETAILS

Unspecified

ASSIGNMENT

Not Applicable

PURPOSE

To collect and assess safety information for the double-blinded treatment period ending 5 years post-randomization regarding deaths, SAEs, adverse events requiring adjudication, and skin ECIs in subjects who were randomized and took at least one dose of blinded study medication, then discontinued from study drug but have not completed follow-up through the 5-year blinded treatment period of Protocol 018 and its 1st extension. These data will be analyzed together with data from subjects who have completed 5 years of blinded study medication.

PHASE

Not Applicable

TARGET SAMPLE SIZE (PHILIPPINES)

55

ACTUAL SAMPLE SIZE (PHILIPPINES)

35

REASON FOR THE DIFFRERENCE BETWEEN TARGET & ACTUAL SAMPLE SIZES

some patients cannot be contacted anymore, some patients declined participation

DATE OF FIRST ENROLLMENT

2014-03-03

RESEARCH UTILIZATION

Utilization	Utilization Info
No records Found.	