MK3207 for Treatment of Acute Migraines (3207-005)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00712725

First received: July 8, 2008
Last updated: January 23, 2015
Last verified: January 2015
History of Changes

Purpose

The purpose of the study is to demonstrate the effectiveness and appropriate dosage level of MK3207 in the treatment of acute migraine.

Condition	Intervention	Phase
Migraine	Drug: MK3207- 2.5 mg Drug: MK3207- 5 mg Drug: MK3207- 10 mg Drug: MK3207- 20 mg Drug: MK3207- 50 mg Drug: MK3207- 100 mg Drug: Comparator: placebo (unspecified)	Phase 2

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

Official Title: A Phase IIb, Multicenter, Randomized, Double-blind, Placebo-Controlled Dose-finding Study of MK3207 in the Treatment of Acute Migraine

Resource links provided by NLM:

MedlinePlus related topics: Migraine

U.S. FDA Resources

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

Primary Outcome Measures:

- Pain Freedom (PF) [Time Frame: 2 hours postdose] [Designated as safety issue: No]

  Reduction of a Grade 2 or 3 severity migraine at baseline to Grade 0 at 2 hours postdose. Rating of Headache Severity (Scale from Grade 0 to 3):
  - Grade 0: No pain
  - Grade 1: Mild pain
  - Grade 2: Moderate pain
  - Grade 3: Severe pain

Secondary Outcome Measures:

- Pain Relief (PR) [Time Frame: 2 hours postdose] [Designated as safety issue: Yes]

  Reduction of a Grade 2 or 3 severity migraine at baseline to mild or no pain (Grade 1 or 0) at 2 hours postdose. Rating of Headache Severity (Scale from Grade 0 to 3):
  - Grade 0: No pain
  - Grade 1: Mild pain
  - Grade 2: Moderate pain
  - Grade 3: Severe pain

- Absence of Photophobia [Time Frame: 2 hours postdose] [Designated as safety issue: Yes]

  Absence of photophobia at 2 hours postdose as recorded by patient on paper diary.

- Absence of Phonophobia [Time Frame: 2 hours postdose] [Designated as safety issue: Yes]

  Absence of phonophobia at 2 hours postdose as recorded by patient on paper diary.

- Absence of Nausea [Time Frame: 2 hours postdose] [Designated as safety issue: Yes]

  Absence of nausea at 2 hours postdose as recorded by patient on paper diary.

- Sustained Pain Freedom (SPF) [Time Frame: 2-24 hours postdose] [Designated as safety issue: Yes]

  Pain freedom (Grade 0) at 2 hours postdose, with no administration of any rescue medication and no occurrence thereafter of a mild/moderate/severe headache during the 2 to 24 hours after dosing with study medication.

Enrollment:	676
Study Start Date:	July 2008
Study Completion Date:	January 2009
Primary Completion Date:	January 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 MK3207- 2.5 mg	Drug: MK3207- 2.5 mg Arm 1: MK3207 2.5 mg taken after migraine onset. Other Name: MK3207
Experimental: 2 MK3207- 5 mg	Drug: MK3207- 5 mg Arm 2: MK3207 5 mg taken after migraine onset. Other Name: MK3207
Experimental: 3 MK3207- 10 mg	Drug: MK3207- 10 mg Arm 3: MK3207 10 mg taken after migraine onset. Other Name: MK3207
Experimental: 4 MK3207- 20 mg	Drug: MK3207- 20 mg Arm 4: MK3207 20 mg taken after migraine onset. Other Name: MK3207

Experimental: 5 MK3207- 50 mg	Drug: MK3207- 50 mg Arm 5: MK3207 50 mg taken after migraine onset. Other Name: MK3207
Experimental: 6 MK3207- 100 mg	Drug: MK3207- 100 mg Arm 6: MK3207 100 mg taken after migraine onset. Other Name: MK3207
Placebo Comparator: 7 Placebo	Drug: Comparator: placebo (unspecified) Placebo taken after migraine onset.

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Men and Women from 18 to 65 years of age
- 1+ year history of migraine that typically last from 4 to 72 hours if untreated
- Had from 2 to 8 moderate or severe migraine attacks per month in the last 2 months
- Not pregnant or planning to become pregnant in next 6 months

Exclusion Criteria:

- Pregnant or breast-feeding, or planning to become pregnant in next 6 months
- Cannot distinguish migraine attacks from tension type headaches
- Migraines are mild or resolve without medication in less than 2 hours
- More than 15 headache-days per month or have taken medication on more than 10 days per month in the last 3 months
- Basilar type or hemiplegic migraine headaches
- More than 50 years old when migraines began
- History of cardiovascular disorder within last 6 months

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.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00712725

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Hewitt DJ, Aurora SK, Dodick DW, Goadsby PJ, Ge YJ, Bachman R, Taraborelli D, Fan X, Assaid C, Lines C, Ho TW. Randomized controlled trial of the CGRP receptor antagonist MK-3207 in the acute treatment of migraine. Cephalalgia. 2011 Apr;31(6):712-22. doi: 10.1177/0333102411398399. Epub 2011 Mar 7.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00712725 History of Changes
Other Study ID Numbers:	3207-005 2008_536
Study First Received:	July 8, 2008
Results First Received:	October 22, 2010
Last Updated:	January 23, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Migraine Disorders	Headache Disorders
Brain Diseases	Headache Disorders, Primary
Central Nervous System Diseases	Nervous System Diseases

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MK3207 for Treatment of Acute Migraines (3207-005)

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ClinicalTrials.gov Identifier:
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First received: July 8, 2008
Last updated: January 23, 2015
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History of Changes

Results First Received: October 22, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Migraine
Interventions:	Drug: MK3207- 2.5 mg Drug: MK3207- 5 mg Drug: MK3207- 10 mg Drug: MK3207- 20 mg Drug: MK3207- 50 mg Drug: MK3207- 100 mg Drug: Comparator: placebo (unspecified)

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
Participants were recruited from 47 neurological and general research centers worldwide (19 in the United States and 28 internationally). The primary therapy period was between 2-Jul-08 to 16-Jan-09.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants were assessed using the protocol inclusion and exclusion criteria at Visit 1 and, if eligible, were randomized at the same visit.

Reporting Groups

	Description

Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.

Participant Flow: Overall Study

	Placebo	MK3207 2.5 mg	MK3207 5 mg	MK3207 10 mg	MK3207 20 mg	MK3207 50 mg	MK3207 100 mg	MK3207 200 mg
STARTED	169	39	57	84	86	84	83	74
COMPLETED	140 [1]	33 [1]	47 [1]	67 [1]	67 [1]	68 [1]	61 [2]	63 [1]
NOT COMPLETED	29	6	10	17	19	16	22	11
Adverse Event	1	0	0	1	0	0	0	0
Lost to Follow-up	3	2	1	1	2	2	3	1
Physician Decision	2	0	0	0	1	0	2	0
Pregnancy	0	1	0	0	1	0	2	0
Protocol Violation	2	0	1	3	2	0	1	1
Withdrawal by Subject	2	1	1	2	1	1	1	2
Lack of Qualifying Event	16	2	6	8	11	13	11	6
Protocol Specified Criteria	3	0	1	2	1	0	2	1

[1] The "Not Completed" patients discontinued prior to receiving study medication.
[2] One patient received study drug. The remaining patients discontinued prior to receiving study drug.

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
Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache. The participants reported in the Baseline Characteristics are randomized participants that received study treatment.

MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache. The participants reported in the Baseline Characteristics are randomized participants that received study treatment.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache. The participants reported in the Baseline Characteristics are randomized participants that received study treatment.
MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache. The participants reported in the Baseline Characteristics are randomized participants that received study treatment.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache. The participants reported in the Baseline Characteristics are randomized participants that received study treatment.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache. The participants reported in the Baseline Characteristics are randomized participants that received study treatment.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache. The participants reported in the Baseline Characteristics are randomized participants that received study treatment.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine headache. The participants reported in the Baseline Characteristics are randomized participants that received study treatment.
Total	Total of all reporting groups

Baseline Measures

	Placebo	MK3207 2.5 mg	MK3207 5 mg	MK3207 10 mg	MK3207 20 mg	MK3207 50 mg	MK3207 100 mg	MK3207 200 mg	Total
Number of Participants [units: participants]	**140**	**33**	**47**	**67**	**67**	**68**	**62**	**63**	**547**
Age [units: years] Mean (Standard Deviation)	**42.1 (11.2)**	**43.3 (10.5)**	**43.4 (11.1)**	**44.1 (10.0)**	**44.1 (11.3)**	**42.2 (10.8)**	**42.2 (10.9)**	**40.5 (10.7)**	**42.7 (10.9)**
Gender [units: participants]									
Female	**125**	**27**	**40**	**62**	**54**	**62**	**52**	**54**	**476**
Male	**15**	**6**	**7**	**5**	**13**	**6**	**10**	**9**	**71**
Ethnicity (NIH/OMB) [units: participants]									
Hispanic or Latino	**15**	**4**	**4**	**4**	**10**	**13**	**9**	**10**	**69**
Not Hispanic or Latino	**125**	**29**	**43**	**63**	**57**	**55**	**53**	**53**	**478**
Unknown or Not Reported	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Race/Ethnicity, Customized [units: participants]									
White	**132**	**32**	**46**	**62**	**63**	**64**	**59**	**59**	**517**
Black	**5**	**0**	**1**	**3**	**1**	**2**	**2**	**3**	**17**
Asian	**1**	**1**	**0**	**0**	**1**	**1**	**1**	**1**	**6**
American Indian or Alaska Native	**1**	**0**	**0**	**1**	**1**	**0**	**0**	**0**	**3**
Native Hawaiian or Other Pacific Islander	**0**	**0**	**0**	**1**	**0**	**1**	**0**	**0**	**2**
Multi-Racial	**1**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**2**
Study Region									

[units: Participants]									
United States	66	14	22	30	39	45	34	20	270
Ex-United States	74	19	25	37	28	23	28	43	277

Outcome Measures

Hide All Outcome Measures

1. Primary: Pain Freedom (PF) [Time Frame: 2 hours postdose]

Measure Type	Primary
Measure Title	Pain Freedom (PF)
Measure Description	Reduction of a Grade 2 or 3 severity migraine at baseline to Grade 0 at 2 hours postdose. Rating of Headache Severity (Scale from Grade 0 to 3): • Grade 0: No pain • Grade 1: Mild pain • Grade 2: Moderate pain • Grade 3: Severe pain
Time Frame	2 hours postdose
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), which included all randomized participants who administered study treatment, had both a baseline severity measurement and at least one postdose efficacy measurement prior to or including the 2-hour time point.

Reporting Groups

	Description
Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.

Measured Values

	Placebo	MK3207 2.5 mg	MK3207 5 mg	MK3207 10 mg	MK3207 20 mg	MK3207 50 mg	MK3207 100 mg	MK3207 200 mg
Number of Participants Analyzed [units: participants]	133	32	44	63	63	65	59	58
Pain Freedom (PF) [units: Participants]	13	4	5	16	12	14	14	21

Statistical Analysis 1 for Pain Freedom (PF)

Groups [1]	All groups
Method [2]	Generalized linear regression model
P Value [3]	<0.001

[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:
	Model adjusted for geographic region (US, ex-US), baseline severity (moderate, severe), treatment and age (continuous), using identity link function.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	p-value constructed from trend test of dose response, by testing the slope of the MK3207 dose covariate (all dose groups included) in a generalized linear regression model with PF at 2 hours postdose as the dependent variable.

2. Secondary: Pain Relief (PR) [Time Frame: 2 hours postdose]

Measure Type	Secondary
Measure Title	Pain Relief (PR)
Measure Description	Reduction of a Grade 2 or 3 severity migraine at baseline to mild or no pain (Grade 1 or 0) at 2 hours postdose. Rating of Headache Severity (Scale from Grade 0 to 3): • Grade 0: No pain • Grade 1: Mild pain • Grade 2: Moderate pain • Grade 3: Severe pain
Time Frame	2 hours postdose
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.
Full Analysis Set (FAS), which included all randomized participants who administered study treatment, had both a baseline severity measurement and at least one postdose efficacy measurement prior to or including the 2-hour time point.

Reporting Groups

	Description
Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine

	headache.

Measured Values

	Placebo	MK3207 2.5 mg	MK3207 5 mg	MK3207 10 mg	MK3207 20 mg	MK3207 50 mg	MK3207 100 mg	MK3207 200 mg
Number of Participants Analyzed [units: participants]	133	32	44	63	63	65	59	58
Pain Relief (PR) [units: Participants]	48	15	19	36	36	41	31	40

Statistical Analysis 1 for Pain Relief (PR)

Groups [1]	All groups
Method [2]	Generalized linear regression model
P Value [3]	<0.001

[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:
	Model adjusted for geographic region (US, ex-US), baseline severity (moderate, severe), treatment and age (continuous), using identity link function.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	p-value constructed from trend test of dose response, by testing the slope of the MK3207 dose covariate (all dose groups included) in a generalized linear regression model with binary response PR at 2 hours postdose as the dependent variable.

3. Secondary: Absence of Photophobia [Time Frame: 2 hours postdose]

Measure Type	Secondary
Measure Title	Absence of Photophobia
Measure Description	Absence of photophobia at 2 hours postdose as recorded by patient on paper diary.
Time Frame	2 hours postdose
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.
Full Analysis Set (FAS), which included all randomized participants who administered study treatment, had both a baseline severity measurement and at least one postdose efficacy measurement prior to or including the 2-hour time point.

Reporting Groups

	Description
Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.

MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.

Measured Values

	Placebo	MK3207 2.5 mg	MK3207 5 mg	MK3207 10 mg	MK3207 20 mg	MK3207 50 mg	MK3207 100 mg	MK3207 200 mg
Number of Participants Analyzed [units: participants]	**133**	**32**	**44**	**63**	**63**	**65**	**59**	**58**
Absence of Photophobia [units: Participants]	**51**	**10**	**15**	**32**	**27**	**32**	**26**	**33**

Statistical Analysis 1 for Absence of Photophobia

Groups [1]	All groups
Method [2]	Generalized linear regression model
P Value [3]	<0.001

[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:
	Model adjusted for geographic region (US, ex-US), baseline severity (moderate, severe), treatment and age (continuous), using identity link function.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	p-value constructed from trend test of dose response, by testing the slope of the MK3207 dose covariate (all dose groups included) in a generalized linear regression model with Absence of Photophobia at 2 hours postdose as the dependent variable.

4. Secondary: Absence of Phonophobia [Time Frame: 2 hours postdose]

Measure Type	Secondary
Measure Title	Absence of Phonophobia
Measure Description	Absence of phonophobia at 2 hours postdose as recorded by patient on paper diary.
Time Frame	2 hours postdose
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.
Full Analysis Set (FAS), which included all randomized participants who administered study treatment, had both a baseline severity measurement and at least one postdose efficacy measurement prior to or including the 2-hour time point.

Reporting Groups

	Description
Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.

Measured Values

	Placebo	MK3207 2.5 mg	MK3207 5 mg	MK3207 10 mg	MK3207 20 mg	MK3207 50 mg	MK3207 100 mg	MK3207 200 mg
Number of Participants Analyzed [units: participants]	**133**	**32**	**44**	**63**	**63**	**65**	**59**	**58**
Absence of Phonophobia [units: Participants]	**57**	**12**	**18**	**35**	**35**	**38**	**31**	**37**

Statistical Analysis 1 for Absence of Phonophobia

Groups [1]	All groups
Method [2]	Generalized linear regression model
P Value [3]	<0.001

[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:
	Model adjusted for geographic region (US, ex-US), baseline severity (moderate, severe), treatment and age (continuous), using identity link function.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	p-value constructed from trend test of dose response, by testing the slope of the MK3207 dose covariate (all dose groups included) in a generalized linear regression model with Absence of Phonophobia at 2 hours postdose as the dependent variable.

5. Secondary: Absence of Nausea [Time Frame: 2 hours postdose]

Measure Type	Secondary
Measure Title	Absence of Nausea
Measure Description	Absence of nausea at 2 hours postdose as recorded by patient on paper diary.
Time Frame	2 hours postdose

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.
Full Analysis Set (FAS), which included all randomized participants who administered study treatment, had both a baseline severity measurement and at least one postdose efficacy measurement prior to or including the 2-hour time point.

Reporting Groups

	Description
Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.

Measured Values

	Placebo	**MK3207 2.5 mg**	**MK3207 5 mg**	**MK3207 10 mg**	**MK3207 20 mg**	**MK3207 50 mg**	**MK3207 100 mg**	**MK3207 200 mg**
Number of Participants Analyzed [units: participants]	**133**	**32**	**43**	**63**	**63**	**65**	**59**	**58**
Absence of Nausea [units: Participants]	**79**	**19**	**25**	**44**	**42**	**44**	**41**	**45**

Statistical Analysis 1 for Absence of Nausea

Groups [1]	All groups
Method [2]	Generalized linear regression model
P Value [3]	0.007

[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:
	Model adjusted for geographic region (US, ex-US), baseline severity (moderate, severe), treatment and age (continuous), using identity link function.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	p-value constructed from trend test of dose response, by testing the slope of the MK3207 dose covariate (all dose groups included) in a generalized linear regression model with Absence of Nausea at 2 hours postdose as the dependent variable.

6. Secondary: Sustained Pain Freedom (SPF) [Time Frame: 2-24 hours postdose]

Measure Type	Secondary
Measure Title	Sustained Pain Freedom (SPF)
Measure Description	Pain freedom (Grade 0) at 2 hours postdose, with no administration of any rescue medication and no occurrence thereafter of a mild/moderate/severe headache during the 2 to 24 hours after dosing with study medication.
Time Frame	2-24 hours postdose
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.
Full Analysis Set (FAS), which included all randomized participants who met the FAS criteria for PF at 2 hours postdose, and who, between 2-24 hours posedose, either 1) did not have PF at any time, 2) used rescue, or 3) answered the 24 hour recurrence question.

Reporting Groups

	Description
Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.

Measured Values

	Placebo	**MK3207 2.5 mg**	**MK3207 5 mg**	**MK3207 10 mg**	**MK3207 20 mg**	**MK3207 50 mg**	**MK3207 100 mg**	**MK3207 200 mg**
Number of Participants Analyzed [units: participants]	**133**	**32**	**44**	**63**	**63**	**65**	**59**	**58**
Sustained Pain Freedom (SPF) [units: Participants]	**10**	**4**	**2**	**13**	**10**	**12**	**12**	**17**

Statistical Analysis 1 for Sustained Pain Freedom (SPF)

Groups [1]	All groups
Method [2]	Generalized linear regression model
P Value [3]	<0.001

[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:
	Model adjusted for geographic region (US, ex-US), baseline severity (moderate, severe), treatment and age (continuous), using identity link function.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	p-value constructed from trend test of dose response, by testing the slope of the MK3207 dose covariate (all dose groups included) in a generalized linear regression model with binary response SPF 2-24 hours postdose as the dependent variable.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Patients were assessed for AEs from V1 (Pre-treatment Screening/Randomization) through 14 days after the dose of study medication was taken. AEs that occurred prior to administration of study medication were not included in AE summaries.
Additional Description	Every patient is counted a single time for each applicable specific adverse event. Patients in population are patients who took at least one tablet of the study medication. Placebo is the pooled arm of all matching placebo doses.

Reporting Groups

	Description
Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.

Serious Adverse Events

	Placebo	MK3207 2.5 mg	MK3207 5 mg	MK3207 10 mg	MK3207 20 mg	MK3207 50 mg	MK3207 100 mg	MK3207 200 mg
Total, serious adverse events								
# participants affected / at risk	**1/142 (0.70%)**	**0/32 (0.00%)**	**0/47 (0.00%)**	**1/66 (1.52%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**
Cardiac disorders								
Cardiac failure congestive * 1								
# participants affected / at risk	**1/142 (0.70%)**	**0/32 (0.00%)**	**0/47 (0.00%)**	**0/0**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**
Immune system disorders								
Hypersensitivity * 1								
# participants affected / at	**1/142 (0.70%)**	**0/32 (0.00%)**	**0/47 (0.00%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**

risk								
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
Ovarian cyst * 1								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**0/47 (0.00%)**	**1/66 (1.52%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (11.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Patients were assessed for AEs from V1 (Pre-treatment Screening/Randomization) through 14 days after the dose of study medication was taken. AEs that occurred prior to administration of study medication were not included in AE summaries.
Additional Description	Every patient is counted a single time for each applicable specific adverse event. Patients in population are patients who took at least one tablet of the study medication. Placebo is the pooled arm of all matching placebo doses.

Frequency Threshold

Threshold above which other adverse events are reported	2%

Reporting Groups

	Description
Placebo	Placebo; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 2.5 mg	MK3207 2.5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 5 mg	MK3207 5 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 10 mg	MK3207 10 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 20 mg	MK3207 20 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 50 mg	MK3207 50 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 100 mg	MK3207 100 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.
MK3207 200 mg	MK3207 200 mg; one orally administered dose to treat a single moderate-to-severe migraine headache.

Other Adverse Events

	Placebo	**MK3207 2.5 mg**	**MK3207 5 mg**	**MK3207 10 mg**	**MK3207 20 mg**	**MK3207 50 mg**	**MK3207 100 mg**	**MK3207 200 mg**
Total, other (not including serious) adverse events								
# participants affected / at risk	**20/142 (14.08%)**	**10/32 (31.25%)**	**18/47 (38.30%)**	**9/66 (13.64%)**	**14/67 (20.90%)**	**16/68 (23.53%)**	**17/62 (27.42%)**	**11/63 (17.46%)**
Cardiac disorders								

Palpitations [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	1/67 (1.49%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Tachycardia [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Ear and labyrinth disorders								
Tinnitus [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	1/62 (1.61%)	0/63 (0.00%)
Vertigo [*1]								
# participants affected / at risk	2/142 (1.41%)	1/32 (3.13%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	2/62 (3.23%)	0/63 (0.00%)
Eye disorders								
Vision blurred [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	0/47 (0.00%)	0/66 (0.00%)	1/67 (1.49%)	0/68 (0.00%)	2/62 (3.23%)	0/63 (0.00%)
Gastrointestinal disorders								
Abdominal discomfort [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Abdominal pain upper [*1]								
# participants affected / at risk	2/142 (1.41%)	0/32 (0.00%)	1/47 (2.13%)	2/66 (3.03%)	0/67 (0.00%)	1/68 (1.47%)	1/62 (1.61%)	0/63 (0.00%)
Diarrhoea [*1]								
# participants affected / at risk	2/142 (1.41%)	1/32 (3.13%)	1/47 (2.13%)	1/66 (1.52%)	0/67 (0.00%)	0/68 (0.00%)	1/62 (1.61%)	0/63 (0.00%)
Dry mouth [*1]								
# participants affected / at risk	3/142 (2.11%)	0/32 (0.00%)	3/47 (6.38%)	1/66 (1.52%)	2/67 (2.99%)	4/68 (5.88%)	0/62 (0.00%)	1/63 (1.59%)
Dyspepsia [*1]								
# participants affected / at risk	1/142 (0.70%)	1/32 (3.13%)	0/47 (0.00%)	0/66 (0.00%)	0/67 (0.00%)	1/68 (1.47%)	1/62 (1.61%)	0/63 (0.00%)

Hypoaesthesia oral [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**1/47 (2.13%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**
Nausea [*1]								
# participants affected / at risk	**5/142 (3.52%)**	**1/32 (3.13%)**	**2/47 (4.26%)**	**3/66 (4.55%)**	**5/67 (7.46%)**	**3/68 (4.41%)**	**5/62 (8.06%)**	**2/63 (3.17%)**
Paraesthesia oral [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**1/47 (2.13%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**
Regurgitation [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**1/47 (2.13%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**
Vomiting [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**3/47 (6.38%)**	**1/66 (1.52%)**	**1/67 (1.49%)**	**0/68 (0.00%)**	**1/62 (1.61%)**	**1/63 (1.59%)**
General disorders								
Chest discomfort [*1]								
# participants affected / at risk	**1/142 (0.70%)**	**0/32 (0.00%)**	**1/47 (2.13%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**1/63 (1.59%)**
Chills [*1]								
# participants affected / at risk	**2/142 (1.41%)**	**1/32 (3.13%)**	**0/47 (0.00%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**
Fatigue [*1]								
# participants affected / at risk	**4/142 (2.82%)**	**1/32 (3.13%)**	**2/47 (4.26%)**	**2/66 (3.03%)**	**2/67 (2.99%)**	**4/68 (5.88%)**	**0/62 (0.00%)**	**2/63 (3.17%)**
Feeling hot [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**0/47 (0.00%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**2/62 (3.23%)**	**0/63 (0.00%)**
Irritability [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**1/47 (2.13%)**	**0/66 (0.00%)**	**2/67 (2.99%)**	**0/68 (0.00%)**	**1/62 (1.61%)**	**0/63 (0.00%)**
Malaise [*1]								
# participants				**0/66 (0.00%)**				

# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)		0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Investigations								
Blood glucose increased [*1]								
# participants affected / at risk	0/142 (0.00%)	1/32 (3.13%)	0/47 (0.00%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Musculoskeletal and connective tissue disorders								
Arthralgia [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	1/68 (1.47%)	0/62 (0.00%)	0/63 (0.00%)
Muscle spasms [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Muscle tightness [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Myalgia [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Pain in extremity [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	0/47 (0.00%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	3/62 (4.84%)	0/63 (0.00%)
Sensation of heaviness [*1]								
# participants affected / at risk	0/142 (0.00%)	1/32 (3.13%)	0/47 (0.00%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Nervous system disorders								
Dizziness [*1]								
# participants affected / at risk	2/142 (1.41%)	3/32 (9.38%)	4/47 (8.51%)	2/66 (3.03%)	2/67 (2.99%)	2/68 (2.94%)	1/62 (1.61%)	2/63 (3.17%)
Dysgeusia [*1]								
# participants affected / at risk	1/142 (0.70%)	1/32 (3.13%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	1/68 (1.47%)	0/62 (0.00%)	0/63 (0.00%)

Headache [*1]								
# participants affected / at risk	0/142 (0.00%)	2/32 (6.25%)	0/47 (0.00%)	0/66 (0.00%)	1/67 (1.49%)	0/68 (0.00%)	3/62 (4.84%)	0/63 (0.00%)
Hyperaesthesia [*1]								
# participants affected / at risk	0/142 (0.00%)	1/32 (3.13%)	0/47 (0.00%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Hypoaesthesia [*1]								
# participants affected / at risk	0/142 (0.00%)	1/32 (3.13%)	0/47 (0.00%)	0/66 (0.00%)	0/67 (0.00%)	2/68 (2.94%)	1/62 (1.61%)	1/63 (1.59%)
Paraesthesia [*1]								
# participants affected / at risk	1/142 (0.70%)	1/32 (3.13%)	0/47 (0.00%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	1/63 (1.59%)
Somnolence [*1]								
# participants affected / at risk	2/142 (1.41%)	1/32 (3.13%)	2/47 (4.26%)	0/66 (0.00%)	2/67 (2.99%)	3/68 (4.41%)	0/62 (0.00%)	0/63 (0.00%)
Tremor [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	1/63 (1.59%)
Psychiatric disorders								
Aggression [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Anxiety [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Insomnia [*1]								
# participants affected / at risk	1/142 (0.70%)	1/32 (3.13%)	0/47 (0.00%)	1/66 (1.52%)	0/67 (0.00%)	1/68 (1.47%)	0/62 (0.00%)	1/63 (1.59%)
Panic attack [*1]								
# participants affected / at risk	0/142 (0.00%)	0/32 (0.00%)	1/47 (2.13%)	0/66 (0.00%)	0/67 (0.00%)	0/68 (0.00%)	0/62 (0.00%)	0/63 (0.00%)
Respiratory, thoracic and mediastinal								

disorders								
Oropharyngeal pain [*1]								
# participants affected / at risk	**1/142 (0.70%)**	**1/32 (3.13%)**	**0/47 (0.00%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**1/62 (1.61%)**	**0/63 (0.00%)**
Throat tightness [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**2/47 (4.26%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**
Yawning [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**1/47 (2.13%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**
Skin and subcutaneous tissue disorders								
Erythema [*1]								
# participants affected / at risk	**1/142 (0.70%)**	**1/32 (3.13%)**	**0/47 (0.00%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**1/63 (1.59%)**
Pruritus [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**1/47 (2.13%)**	**0/66 (0.00%)**	**1/67 (1.49%)**	**1/68 (1.47%)**	**0/62 (0.00%)**	**1/63 (1.59%)**
Urticaria [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**1/47 (2.13%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**0/63 (0.00%)**
Vascular disorders								
Flushing [*1]								
# participants affected / at risk	**1/142 (0.70%)**	**0/32 (0.00%)**	**1/47 (2.13%)**	**0/66 (0.00%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**1/63 (1.59%)**
Hot flush [*1]								
# participants affected / at risk	**0/142 (0.00%)**	**0/32 (0.00%)**	**0/47 (0.00%)**	**1/66 (1.52%)**	**0/67 (0.00%)**	**0/68 (0.00%)**	**0/62 (0.00%)**	**2/63 (3.17%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (11.1)

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: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
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Publications of Results:

Hewitt DJ, Aurora SK, Dodick DW, Goadsby PJ, Ge YJ, Bachman R, Taraborelli D, Fan X, Assaid C, Lines C, Ho TW. Randomized controlled trial of the CGRP receptor antagonist MK-3207 in the acute treatment of migraine. Cephalalgia. 2011 Apr;31(6):712-22. doi: 10.1177/0333102411398399. Epub 2011 Mar 7.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00712725 History of Changes
Other Study ID Numbers:	3207-005 2008_536
Study First Received:	July 8, 2008
Results First Received:	October 22, 2010
Last Updated:	January 23, 2015
Health Authority:	United States: Food and Drug Administration

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