Multiple Attacks Study to Compare the Efficacy and Safety of MK-0974 With Placebo for Acute Migraine (MK-0974-031)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00483704

First received: May 15, 2007
Last updated: June 23, 2015
Last verified: June 2015
History of Changes

Purpose

The purpose of the study is to assess the safety and efficacy of telcagepant (MK-0974) in acute treatment of multiple migraine attacks with or without aura. Primary hypotheses of this study are that telcagepant is superior to placebo, as measured by the proportion of participants who have pain freedom, pain relief, pain freedom consistency, pain relief consistency, and absence of photophobia, phonophobia, and nausea at 2 hours post-dose.

Condition	Intervention	Phase
Migraines	Drug: Telcagepant 140 mg Drug: Talcagepant 280 mg Drug: Placebo	Phase 3

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 Multicenter, Double-Blind, Placebo-Controlled, Parallel Group Multiple Attacks Study to Compare the Efficacy and Safety of Oral MK-0974 With Placebo for the Acute Treatment of Migraine With or Without Aura

Resource links provided by NLM:

MedlinePlus related topics: Headache Migraine

U.S. FDA Resources

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

Primary Outcome Measures:

- Percentage of Participants Reporting Pain Freedom at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: No]

  Pain Freedom (PF) at 2 hours post-dose (first migraine attack), with pain freedom defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 0 at 2 hours post-dose. Headache severity was subjectively rated by the participant at predefined time points on a scale of Grade 0 to Grade 3: Grade 0 - No pain; Grade 1 - Mild pain; Grade 2 - Moderate Pain; and Grade 3 - Severe Pain.

- Percentage of Participants Reporting Pain Relief at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: No]

  Pain Relief (PR) at 2 hours post-dose (first migraine attack), with pain relief defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 1/0 at 2 hours post-dose. Headache severity was subjectively rated by the participant at predefined time points on a scale of Grade 0 to Grade 3: Grade 0 - No pain; Grade 1 - Mild pain; Grade 2 - Moderate Pain; and Grade 3 - Severe Pain.

- Percentage of Participants Reporting Pain Freedom Consistency at 2 Hours Post-dose [Time Frame: 2 hours post-dose (up to 6 months)] [Designated as safety issue: No]

  Pain Freedom Consistency (PFC) at 2 hours post-dose, defined as having achieved PF at 2 hours post-dose on at least 3 treated migraine attacks. Note that for the control groups, a positive PF response arising from the administration of the 1 talcagepant treated migraine attack will count as one of the 3 positive PF responses needed to fulfill the criteria for PFC.

- Percentage of Participants Reporting Pain Relief Consistency at 2 Hours Post-dose [Time Frame: 2 hours post-dose (up to 6 months)] [Designated as safety issue: No]

  Pain Relief Consistency (PRC) at 2 hours post-dose, defined as having achieved PR at 2 hours post-dose on at least 3 treated migraine attacks. Note that for the control groups, a positive PR response arising from the administration of the 1 telcagepant treated migraine attack will count as one of the 3 positive PR responses needed to fulfill the criteria for PRC.

- Percentage of Participants Reporting Absence of Photophobia at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: No]

  The participant recorded whether photophobia (sensitivity to light) was present or absent at each of the predefined time points.

- Percentage of Participants Reporting Absence of Phonophobia at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: No]

  The participant recorded whether phonophobia (sensitivity to sound) was present or absent at each of the predefined time points.

- Percentage of Participants Reporting Absence of Nausea 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: No]

  The participant recorded whether nausea was present or absent at each of the predefined time points.

- Number of Participants Experiencing an Adverse Event (AE) Within 48 Hours Post-dose (First Migraine Attack) [Time Frame: Up to 48 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: Yes]

  AEs were reported following treatment for the first migraine attack using a 48-hour post-dose window. AEs displayed are those reported by at least 4 participants in one or more treatment groups.

- Number of Participants Discontinuing Study Medication Due to an AE [Time Frame: Up to the 4th dose of study medication (up to 6 months)] [Designated as safety issue: Yes]

  Participants discontinuing study medication due to an AE were reported for all migraine attacks.

Secondary Outcome Measures:

- Percentage of Participants Reporting Sustained Pain Freedom From 2 to 24 Hours Post-dose (First Migraine Attack) [Time Frame: From 2 to 24 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: No]

  Sustained Pain Freedom (SPF) from 2 to 24 hours after study medication administration. SPF from 2 to 24 hours post-dose is defined as PF at 2 hours, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache during the 2 to 24 hours after dosing with the study medication.

- Percentage of Participants Reporting Sustained Pain Freedom From 2 to 48 Hours Post-dose (First Migraine Attack) [Time Frame: From 2 to 48 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: No]

Sustained Pain Freedom (SPF) from 2 to 48 hours post-dose after study medication administration. SPF from 2 to 48 hours post-dose is defined as PF at 2 hours, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache during the 2 to 48 hours after dosing with the study medication.

- Percentage of Participants Reporting Total Migraine Freedom at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: No]

  TMF 2 hours post-dose, which is defined as TMF at 2 hours post-dose, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache and no reported occurrence of photophobia, phonophobia, nausea, or vomiting during the 2 hours after dosing with the study medication.

- Percentage of Participants Reporting Total Migraine Freedom From 2 to 24 Hours Post-dose (First Migraine Attack) [Time Frame: From 2 to 24 hours post-dose for the first migraine attack (up to 6 months)] [Designated as safety issue: No]

  TMF from 2 to 24 hours post-dose, which is defined as TMF at 2 hours post-dose, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache and no reported occurrence of photophobia, phonophobia, nausea, or vomiting during the 2 to 24 hours after dosing with the study medication.

Enrollment:	1935
Study Start Date:	August 2008
Study Completion Date:	March 2009
Primary Completion Date:	March 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Telcagepant 140 mg Telcagepant 140 mg, oral, tablet, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.	Drug: Telcagepant 140 mg Telcagepant 140 mg tablets
Experimental: Telcagepant 280 mg Telcagepant 280 mg, oral, tablet, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.	Drug: Talcagepant 280 mg Telcagepant 280 mg tablets
Placebo Comparator: Control Group 1 Placebo, oral, tablet, across 3 migraine attacks (1st, 2nd, and 4th). Telcagepant 140 mg will be administered for the 3rd migraine attack. Participants will receive placebo for the optional second dose. For migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.	Drug: Telcagepant 140 mg Telcagepant 140 mg tablets Drug: Placebo Placebo tablets
Placebo Comparator: Control Group 2 Placebo, oral, tablet, across 3 migraine attacks (1st, 2nd, and 3rd). Telcagepant 140 mg will be administered for the 4th migraine attack. Participants will receive placebo for the optional second dose. For migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.	Drug: Telcagepant 140 mg Telcagepant 140 mg tablets Drug: Placebo Placebo tablets

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- History of migraines within the past year
- 1 to 8 moderate or severe migraine attacks per month in the past 2 months that lasted between 4 to 72 hours if untreated
- Use acceptable contraception throughout the study
- Able to complete the study questionnaire(s) and paper diary
- Limit consumption of grapefruit juice to no more than one 8 ounce glass a day

Exclusion Criteria:

- Pregnant or breast-feeding or is expecting to become pregnant during the study
- Difficulty distinguishing his/her migraine attacks from tension or interval headaches
- A history of mostly mild migraine attacks or migraines that usually resolve spontaneously in less than 2 hours
- More than 15 headache-days per month or has taken medication for acute headache on more than 10 days a month in the past 3 months
- Greater than 50 years old at the age of migraine onset
- Previously taken telcagepant

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: NCT00483704

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Ho AP, Dahlöf CG, Silberstein SD, Saper JR, Ashina M, Kost JT, Froman S, Leibensperger H, Lines CR, Ho TW. Randomized, controlled trial of telcagepant over four migraine attacks. Cephalalgia. 2010 Dec;30(12):1443-57. doi: 10.1177/0333102410370878. Epub 2010 Jun 8.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00483704 History of Changes
Other Study ID Numbers:	0974-031 MK-0974-031 2007_546
Study First Received:	May 15, 2007
Results First Received:	July 14, 2014
Last Updated:	June 23, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
multiple attacks of moderate to severe migraine headaches

Additional relevant MeSH terms:

Migraine Disorders
Brain Diseases
Central Nervous System Diseases

Headache Disorders
Headache Disorders, Primary
Nervous System Diseases

ClinicalTrials.gov processed this record on April 14, 2016

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Results First Received: July 14, 2014

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:	Migraines
Interventions:	Drug: Telcagepant 140 mg Drug: Talcagepant 280 mg Drug: Placebo

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
No text entered.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Participant Flow for 2 periods

Period 1: Randomization

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
STARTED	644	645	646
COMPLETED	573	549	555
NOT COMPLETED	71	96	91
Withdrawal by Subject	19	28	18
Protocol Violation	14	25	22
Lost to Follow-up	14	14	19
Pregnancy	1	0	0
Physician Decision	2	4	0
Progressive disease	0	0	1
Lack of qualifying migraines	21	25	31

Period 2: Treatment

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
STARTED	573	549	555
COMPLETED	444	420	399
NOT COMPLETED	129	129	156
Lack of qualifying migraines	101	99	116
Adverse Event	3	5	4
Withdrawal by Subject	16	12	21
Protocol Violation	6	3	5
Lost to Follow-up	2	7	5
Lack of Efficacy	1	1	1

Pregnancy	**0**	**1**	**0**
Physician Decision	**0**	**1**	**4**

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
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.
Total	Total of all reporting groups

Baseline Measures

	Telcagepant 140 mg	**Telcagepant 280 mg**	**Placebo**	**Total**
Number of Participants [units: participants]	**644**	**645**	**646**	**1935**
Age [units: Years] Mean (Standard Deviation)	**43.2 (11.7)**	**42.6 (11.8)**	**41.9 (11.7)**	**42.6 (11.8)**
Gender [units: Participants]				
Female	**542**	**549**	**540**	**1631**
Male	**102**	**96**	**106**	**304**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Reporting Pain Freedom at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Primary
Measure Title	Percentage of Participants Reporting Pain Freedom at 2 Hours Post-dose (First Migraine Attack)

Measure Description	Pain Freedom (PF) at 2 hours post-dose (first migraine attack), with pain freedom defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 0 at 2 hours post-dose. Headache severity was subjectively rated by the participant at predefined time points on a scale of Grade 0 to Grade 3: Grade 0 - No pain; Grade 1 - Mild pain; Grade 2 - Moderate Pain; and Grade 3 - Severe Pain.
Time Frame	2 hours post-dose for the first migraine attack (up to 6 months)
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 full-analysis set (FAS) included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy measurement for pain severity prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline pain score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	**Telcagepant 280 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**556**	**534**	**539**
Percentage of Participants Reporting Pain Freedom at 2 Hours Post-dose (First Migraine Attack) [units: Percentage of participants]	**21.9**	**25.1**	**10.2**

Statistical Analysis 1 for Percentage of Participants Reporting Pain Freedom at 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.54
95% Confidence Interval	1.80 to 3.58

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Pain Freedom at 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.03
95% Confidence Interval	2.15 to 4.27

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

2. Primary: Percentage of Participants Reporting Pain Relief at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Primary
Measure Title	Percentage of Participants Reporting Pain Relief at 2 Hours Post-dose (First Migraine Attack)
Measure Description	Pain Relief (PR) at 2 hours post-dose (first migraine attack), with pain relief defined as a reduction in headache severity from Grade 3/2 at baseline to Grade 1/0 at 2 hours post-dose. Headache severity was subjectively rated by the participant at predefined time points on a scale of Grade 0 to Grade 3: Grade 0 - No pain; Grade 1 - Mild pain; Grade 2 - Moderate Pain; and Grade 3 - Severe Pain.
Time Frame	2 hours post-dose for the first migraine attack (up to 6 months)
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 FAS Population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy

measurement for pain severity prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline pain score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
Number of Participants Analyzed [units: participants]	**556**	**534**	**539**
Percentage of Participants Reporting Pain Relief at 2 Hours Post-dose (First Migraine Attack) [units: Percentage of participants]	**58.6**	**56.7**	**33.4**

Statistical Analysis 1 for Percentage of Participants Reporting Pain Relief at 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.03
95% Confidence Interval	2.35 to 3.90

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Pain Relief at 2 Hours Post-dose (First Migraine Attack)

[1]	

Groups	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.80
95% Confidence Interval	2.17 to 3.61

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

3. Primary: Percentage of Participants Reporting Pain Freedom Consistency at 2 Hours Post-dose [Time Frame: 2 hours post-dose (up to 6 months)]

Measure Type	Primary
Measure Title	Percentage of Participants Reporting Pain Freedom Consistency at 2 Hours Post-dose
Measure Description	Pain Freedom Consistency (PFC) at 2 hours post-dose, defined as having achieved PF at 2 hours post-dose on at least 3 treated migraine attacks. Note that for the control groups, a positive PF response arising from the administration of the 1 talcagepant treated migraine attack will count as one of the 3 positive PF responses needed to fulfill the criteria for PFC.
Time Frame	2 hours post-dose (up to 6 months)
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 modified FAS (MFAS) Population consisted of all participants who experienced at least either 2 failures or 3 successes, regardless of whether or not they had data for 4 migraine attacks, and recorded baseline severity for at least 1 of the treated migraine attacks.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3

	migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
Number of Participants Analyzed [units: participants]	**493**	**468**	**485**
Percentage of Participants Reporting Pain Freedom Consistency at 2 Hours Post-dose [units: Percentage of participants]	**9.3**	**14.1**	**2.7**

Statistical Analysis 1 for Percentage of Participants Reporting Pain Freedom Consistency at 2 Hours Post-dose

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.85
95% Confidence Interval	2.05 to 7.23

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Pain Freedom Consistency at 2 Hours Post-dose

Groups [1]	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	6.18
95% Confidence Interval	3.36 to 11.39

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.

[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

4. Primary: Percentage of Participants Reporting Pain Relief Consistency at 2 Hours Post-dose [Time Frame: 2 hours post-dose (up to 6 months)]

Measure Type	Primary
Measure Title	Percentage of Participants Reporting Pain Relief Consistency at 2 Hours Post-dose
Measure Description	Pain Relief Consistency (PRC) at 2 hours post-dose, defined as having achieved PR at 2 hours post-dose on at least 3 treated migraine attacks. Note that for the control groups, a positive PR response arising from the administration of the 1 telcagepant treated migraine attack will count as one of the 3 positive PR responses needed to fulfill the criteria for PRC.
Time Frame	2 hours post-dose (up to 6 months)
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 MFAS Population was defined as all participants who experienced at least either 2 failures or 3 successes, regardless of whether or not they had data for 4 migraine attacks, and recorded baseline severity for at least 1 of the treated migraine attacks.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	**Telcagepant 280 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**469**	**440**	**452**
Percentage of Participants Reporting Pain Relief Consistency at 2 Hours Post-dose [units: Percentage of participants]	**41.8**	**46.8**	**22.3**

Statistical Analysis 1 for Percentage of Participants Reporting Pain Relief Consistency at 2 Hours Post-dose

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.62
95% Confidence Interval	1.96 to 3.51

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Pain Relief Consistency at 2 Hours Post-dose

Groups [1]	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.23
95% Confidence Interval	2.41 to 4.34

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

5. Primary: Percentage of Participants Reporting Absence of Photophobia at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Primary
Measure Title	Percentage of Participants Reporting Absence of Photophobia at 2 Hours Post-dose (First Migraine Attack)

Measure Description	The participant recorded whether photophobia (sensitivity to light) was present or absent at each of the predefined time points.
Time Frame	2 hours post-dose for the first migraine attack (up to 6 months)
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 FAS Population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose measurement for photophobia severity prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline photophobia score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	**Telcagepant 280 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**554**	**534**	**539**
Percentage of Participants Reporting Absence of Photophobia at 2 Hours Post-dose (First Migraine Attack) [units: Percentage of participants]	**52.3**	**52.4**	**40.6**

Statistical Analysis 1 for Percentage of Participants Reporting Absence of Photophobia at 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	1.65
95% Confidence Interval	1.30 to 2.11

[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:

	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Absence of Photophobia at 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	1.67
95% Confidence Interval	1.31 to 2.14

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

6. Primary: Percentage of Participants Reporting Absence of Phonophobia at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Primary
Measure Title	Percentage of Participants Reporting Absence of Phonophobia at 2 Hours Post-dose (First Migraine Attack)
Measure Description	The participant recorded whether phonophobia (sensitivity to sound) was present or absent at each of the predefined time points.
Time Frame	2 hours post-dose for the first migraine attack (up to 6 months)
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 FAS Population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose phonophobia measurement prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline phonophobia score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
Number of Participants Analyzed [units: participants]	**555**	**534**	**537**
Percentage of Participants Reporting Absence of Phonophobia at 2 Hours Post-dose (First Migraine Attack) [units: Percentage of participants]	**61.4**	**59.4**	**48.6**

Statistical Analysis 1 for Percentage of Participants Reporting Absence of Phonophobia at 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	1.74
95% Confidence Interval	1.36 to 2.22

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Absence of Phonophobia at 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001

Odds Ratio (OR) [4]	1.61
95% Confidence Interval	1.26 to 2.06

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

7. Primary: Percentage of Participants Reporting Absence of Nausea 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Primary
Measure Title	Percentage of Participants Reporting Absence of Nausea 2 Hours Post-dose (First Migraine Attack)
Measure Description	The participant recorded whether nausea was present or absent at each of the predefined time points.
Time Frame	2 hours post-dose for the first migraine attack (up to 6 months)
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 FAS Population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose measurement for nausea severity prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline nausea score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
Number of Participants Analyzed [units: participants]	**553**	**534**	**538**
Percentage of Participants Reporting Absence of Nausea 2 Hours Post-dose (First Migraine Attack) [units: Percentage of participants]	**72.9**	**71.7**	**62.8**

Statistical Analysis 1 for Percentage of Participants Reporting Absence of Nausea 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	1.67
95% Confidence Interval	1.28 to 2.17

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Absence of Nausea 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	1.57
95% Confidence Interval	1.21 to 2.04

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

8. Primary: Number of Participants Experiencing an Adverse Event (AE) Within 48 Hours Post-dose (First Migraine Attack) [Time Frame: Up to 48 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Primary
Measure Title	Number of Participants Experiencing an Adverse Event (AE) Within 48 Hours Post-dose (First Migraine Attack)
Measure Description	AEs were reported following treatment for the first migraine attack using a 48-hour post-dose window. AEs displayed are those reported by at least 4 participants in one or more treatment groups.
Time Frame	Up to 48 hours post-dose for the first migraine attack (up to 6 months)
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.
The All-Patients-as-Treated (APaT) Population consisted of all participants who received at least 1 dose of study medication and were included in the treatment group according to the medication actually received. If a participant took an unassigned study medication for the first migraine attack, they were included in that treatment group.

Reporting Groups

	Description
Telcagepant 140 mg	Participants who received at least one dose of telcagepant 140 mg.
Telcagepant 280 mg	Participants who received at least one dose of telcagepant 280 mg.
Placebo	Participants who received at least one dose of placebo.

Measured Values

	Telcagepant 140 mg	**Telcagepant 280 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**575**	**538**	**564**
Number of Participants Experiencing an Adverse Event (AE) Within 48 Hours Post-dose (First Migraine Attack) [units: Participants]	**179**	**167**	**157**

No statistical analysis provided for Number of Participants Experiencing an Adverse Event (AE) Within 48 Hours Post-dose (First Migraine Attack)

9. Primary: Number of Participants Discontinuing Study Medication Due to an AE [Time Frame: Up to the 4th dose of study medication (up to 6 months)]

Measure Type	Primary
Measure Title	Number of Participants Discontinuing Study Medication Due to an AE

Measure Description	Participants discontinuing study medication due to an AE were reported for all migraine attacks.
Time Frame	Up to the 4th dose of study medication (up to 6 months)
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.
The APaT Population consisted of all participants who received at least 1 dose of study medication and were included in the treatment group according to the medication actually received. If a participant took an unassigned study medication, they were included in that treatment group.

Reporting Groups

	Description
Telcagepant 140 mg	Participants who received at least one dose of telcagepant 140 mg.
Telcagepant 280 mg	Participants who received at least one dose of telcagepant 280 mg.
Placebo	Participants who received at least one dose of placebo.

Measured Values

	Telcagepant 140 mg	**Telcagepant 280 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**573**	**543**	**561**
Number of Participants Discontinuing Study Medication Due to an AE [units: Participants]	**3**	**5**	**4**

No statistical analysis provided for Number of Participants Discontinuing Study Medication Due to an AE

10. Secondary: Percentage of Participants Reporting Sustained Pain Freedom From 2 to 24 Hours Post-dose (First Migraine Attack) [Time Frame: From 2 to 24 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Secondary
Measure Title	Percentage of Participants Reporting Sustained Pain Freedom From 2 to 24 Hours Post-dose (First Migraine Attack)
Measure Description	Sustained Pain Freedom (SPF) from 2 to 24 hours after study medication administration. SPF from 2 to 24 hours post-dose is defined as PF at 2 hours, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache during the 2 to 24 hours after dosing with the study medication.
Time Frame	From 2 to 24 hours post-dose for the first migraine attack (up to 6 months)
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 FAS Population was participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy

measurement for pain severity prior to, or including, the 2-hr. time point. Participants were excluded from this analysis for not having a baseline pain score, post-dose data through 24 hrs, or a recurrence question.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
Number of Participants Analyzed [units: participants]	**553**	**529**	**537**
Percentage of Participants Reporting Sustained Pain Freedom From 2 to 24 Hours Post-dose (First Migraine Attack) [units: Percentage of participants]	**15.6**	**19.1**	**6.5**

Statistical Analysis 1 for Percentage of Participants Reporting Sustained Pain Freedom From 2 to 24 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.69
95% Confidence Interval	1.78 to 4.07

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Sustained Pain Freedom From 2 to 24 Hours Post-dose (First Migraine Attack)

[1]	

Groups	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.45
95% Confidence Interval	2.30 to 5.19

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

11. Secondary: Percentage of Participants Reporting Sustained Pain Freedom From 2 to 48 Hours Post-dose (First Migraine Attack) [Time Frame: From 2 to 48 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Secondary
Measure Title	Percentage of Participants Reporting Sustained Pain Freedom From 2 to 48 Hours Post-dose (First Migraine Attack)
Measure Description	Sustained Pain Freedom (SPF) from 2 to 48 hours post-dose after study medication administration. SPF from 2 to 48 hours post-dose is defined as PF at 2 hours, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache during the 2 to 48 hours after dosing with the study medication.
Time Frame	From 2 to 48 hours post-dose for the first migraine attack (up to 6 months)
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 FAS Population was participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy measurement for pain severity prior to, or including, the 2-hr. time point. Participants were excluded from this analysis for not having a baseline pain score, post-dose data through 48 hrs, or a recurrence question.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.

Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
Number of Participants Analyzed [units: participants]	**552**	**526**	**536**
Percentage of Participants Reporting Sustained Pain Freedom From 2 to 48 Hours Post-dose (First Migraine Attack) [units: Percentage of participants]	**13.4**	**17.9**	**6.2**

Statistical Analysis 1 for Percentage of Participants Reporting Sustained Pain Freedom From 2 to 48 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.40
95% Confidence Interval	1.56 to 3.69

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Sustained Pain Freedom From 2 to 48 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.37
95% Confidence Interval	2.22 to 5.12

[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:

	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

12. Secondary: Percentage of Participants Reporting Total Migraine Freedom at 2 Hours Post-dose (First Migraine Attack) [Time Frame: 2 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Secondary
Measure Title	Percentage of Participants Reporting Total Migraine Freedom at 2 Hours Post-dose (First Migraine Attack)
Measure Description	TMF 2 hours post-dose, which is defined as TMF at 2 hours post-dose, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache and no reported occurrence of photophobia, phonophobia, nausea, or vomiting during the 2 hours after dosing with the study medication.
Time Frame	2 hours post-dose for the first migraine attack (up to 6 months)
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 FAS Population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy measurement for pain severity prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline pain score or post-dose data through 2 hours.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	**Telcagepant 280 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**556**	**534**	**539**
Percentage of Participants Reporting Total Migraine Freedom at 2 Hours Post-dose (First Migraine Attack)	**19.4**	**22.3**	**9.5**

[units: Percentage of participants]			

Statistical Analysis 1 for Percentage of Participants Reporting Total Migraine Freedom at 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.36
95% Confidence Interval	1.65 to 3.38

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Total Migraine Freedom at 2 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.81
95% Confidence Interval	1.97 to 4.01

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

13. Secondary: Percentage of Participants Reporting Total Migraine Freedom From 2 to 24 Hours Post-dose (First Migraine Attack) [Time Frame: From 2 to 24 hours post-dose for the first migraine attack (up to 6 months)]

Measure Type	Secondary
Measure Title	Percentage of Participants Reporting Total Migraine Freedom From 2 to 24 Hours Post-dose (First Migraine Attack)
Measure Description	TMF from 2 to 24 hours post-dose, which is defined as TMF at 2 hours post-dose, with no administration of either rescue medication or the optional second dose and with no occurrence thereafter of a mild/moderate/severe headache and no reported occurrence of photophobia, phonophobia, nausea, or vomiting during the 2 to 24 hours after dosing with the study medication.
Time Frame	From 2 to 24 hours post-dose for the first migraine attack (up to 6 months)
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 FAS Population included participants treated that migraine attack, and had both a baseline value and at least 1 post-dose efficacy measurement for pain severity prior to, or including, the 2-hour time point. Participants were excluded from this analysis who did not have a baseline pain score or post-dose data through 24 hours.

Reporting Groups

	Description
Telcagepant 140 mg	Telcagepant 140 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 140 mg or placebo.
Telcagepant 280 mg	Telcagepant 280 mg, oral, across 4 migraine attacks. For migraine attack 1 only, if no headache relief is obtained after 2 hours post dose, or if the migraine recurs after 2 hours of the initial treatment, participants may receive an optional second dose of telcagepant 280 mg or placebo.
Placebo	The placebo group is comprised of Control Group 1 and Control Group 2. Control Group 1 receives placebo across 3 migraine attacks (1st, 2nd, and 4th) and telcagepant 140 mg for the 3rd migraine attack. Control Group 2 receives placebo across 3 migraine attacks (1st, 2nd, and 3rd) and telcagepant 140 mg for the 4th migraine attack. For both groups for migraine attacks 2, 3, and 4, no study medication will be provided as an optional second dose.

Measured Values

	Telcagepant 140 mg	**Telcagepant 280 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**553**	**531**	**537**
Percentage of Participants Reporting Total Migraine Freedom From 2 to 24 Hours Post-dose (First Migraine Attack) [units: Percentage of participants]	**13.7**	**17.1**	**6.5**

Statistical Analysis 1 for Percentage of Participants Reporting Total Migraine Freedom From 2 to 24 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 140 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.32
95% Confidence Interval	1.52 to 3.54

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Statistical Analysis 2 for Percentage of Participants Reporting Total Migraine Freedom From 2 to 24 Hours Post-dose (First Migraine Attack)

Groups [1]	Telcagepant 280 mg vs. Placebo
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.02
95% Confidence Interval	2.00 to 4.56

[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:
	Computed using a logistic regression model adjusting for geographic region, baseline migraine severity, and age.
[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:
	An odds ratio >1 is in favor of the first treatment group of the corresponding pairwise comparison.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 14 days post-dose (up to 6 1/2 months)
Additional Description	The APaT Population consisted of all participants who received at least 1 dose of study medication and were included in the treatment group according to the medication actually received. If a participant took an unassigned study medication, they were included in that treatment group.

Reporting Groups

	Description
Telcagepant 140 mg	Participants who received at least one dose of telcagepant 140 mg.

Telcagepant 280 mg	Participants who received at least one dose of telcagepant 280 mg.
Placebo	Participants who received at least one dose of placebo.

Serious Adverse Events

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
Total, serious adverse events			
# participants affected / at risk	**8/573 (1.40%)**	**8/543 (1.47%)**	**4/561 (0.71%)**
Cardiac disorders			
Angina pectoris † 1			
# participants affected / at risk	**1/573 (0.17%)**	**0/543 (0.00%)**	**0/561 (0.00%)**
# events	**1**	**0**	**0**
Palpitations † 1			
# participants affected / at risk	**0/573 (0.00%)**	**1/543 (0.18%)**	**0/561 (0.00%)**
# events	**0**	**1**	**0**
Gastrointestinal disorders			
Abdominal hernia † 1			
# participants affected / at risk	**1/573 (0.17%)**	**0/543 (0.00%)**	**0/561 (0.00%)**
# events	**1**	**0**	**0**
Abdominal pain upper † 1			
# participants affected / at risk	**1/573 (0.17%)**	**0/543 (0.00%)**	**0/561 (0.00%)**
# events	**1**	**0**	**0**
Mallory-Weiss syndrome † 1			
# participants affected / at risk	**0/573 (0.00%)**	**0/543 (0.00%)**	**1/561 (0.18%)**
# events	**0**	**0**	**1**
Hepatobiliary disorders			
Cholecystitis † 1			
# participants affected / at risk	**0/573 (0.00%)**	**1/543 (0.18%)**	**0/561 (0.00%)**
# events	**0**	**1**	**0**
Infections and infestations			
Pneumonia † 1			
# participants affected / at risk	**1/573 (0.17%)**	**1/543 (0.18%)**	**0/561 (0.00%)**
# events	**1**	**1**	**0**
Subcutaneous abscess † 1			
# participants affected / at risk	**1/573 (0.17%)**	**0/543 (0.00%)**	**0/561 (0.00%)**
# events	**1**	**0**	**0**
Investigations			
Platelet count increased † 1			
# participants affected / at risk	**0/573 (0.00%)**	**0/543 (0.00%)**	**1/561 (0.18%)**
# events	**0**	**0**	**1**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
† 1			

Bladder cancer			
# participants affected / at risk	**0/573 (0.00%)**	**0/543 (0.00%)**	**1/561 (0.18%)**
# events	**0**	**0**	**1**
Hodgkin's disease † 1			
# participants affected / at risk	**0/573 (0.00%)**	**1/543 (0.18%)**	**0/561 (0.00%)**
# events	**0**	**1**	**0**
Nervous system disorders			
Cerebrovascular accident † 1			
# participants affected / at risk	**1/573 (0.17%)**	**0/543 (0.00%)**	**0/561 (0.00%)**
# events	**1**	**0**	**0**
Dizziness † 1			
# participants affected / at risk	**0/573 (0.00%)**	**1/543 (0.18%)**	**0/561 (0.00%)**
# events	**0**	**1**	**0**
Dysarthria † 1			
# participants affected / at risk	**0/573 (0.00%)**	**0/543 (0.00%)**	**1/561 (0.18%)**
# events	**0**	**0**	**1**
Hemiplegia † 1			
# participants affected / at risk	**0/573 (0.00%)**	**0/543 (0.00%)**	**1/561 (0.18%)**
# events	**0**	**0**	**1**
Migraine † 1			
# participants affected / at risk	**0/573 (0.00%)**	**3/543 (0.55%)**	**0/561 (0.00%)**
# events	**0**	**3**	**0**
Renal and urinary disorders			
Renal colic † 1			
# participants affected / at risk	**0/573 (0.00%)**	**1/543 (0.18%)**	**0/561 (0.00%)**
# events	**0**	**1**	**0**
Reproductive system and breast disorders			
Dysfunctional uterine bleeding † 1			
# participants affected / at risk	**1/573 (0.17%)**	**0/543 (0.00%)**	**0/561 (0.00%)**
# events	**1**	**0**	**0**
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism † 1			
# participants affected / at risk	**0/573 (0.00%)**	**1/543 (0.18%)**	**0/561 (0.00%)**
# events	**0**	**1**	**0**
Vascular disorders			
Aneurysm † 1			
# participants affected / at risk	**1/573 (0.17%)**	**0/543 (0.00%)**	**0/561 (0.00%)**
# events	**1**	**0**	**0**
Deep vein thrombosis † 1			
# participants affected / at risk	**0/573 (0.00%)**	**1/543 (0.18%)**	**0/561 (0.00%)**
# events	**0**	**1**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 14 days post-dose (up to 6 1/2 months)
Additional Description	The APaT Population consisted of all participants who received at least 1 dose of study medication and were included in the treatment group according to the medication actually received. If a participant took an unassigned study medication, they were included in that treatment group.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Telcagepant 140 mg	Participants who received at least one dose of telcagepant 140 mg.
Telcagepant 280 mg	Participants who received at least one dose of telcagepant 280 mg.
Placebo	Participants who received at least one dose of placebo.

Other Adverse Events

	Telcagepant 140 mg	Telcagepant 280 mg	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**166/573 (28.97%)**	**144/543 (26.52%)**	**138/561 (24.60%)**
Gastrointestinal disorders			
Dry mouth † 1			
# participants affected / at risk	**61/573 (10.65%)**	**42/543 (7.73%)**	**53/561 (9.45%)**
# events	**98**	**82**	**105**
Nausea † 1			
# participants affected / at risk	**44/573 (7.68%)**	**47/543 (8.66%)**	**37/561 (6.60%)**
# events	**59**	**65**	**54**
General disorders			
Fatigue † 1			
# participants affected / at risk	**48/573 (8.38%)**	**34/543 (6.26%)**	**27/561 (4.81%)**
# events	**64**	**43**	**44**
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	**36/573 (6.28%)**	**40/543 (7.37%)**	**40/561 (7.13%)**
# events	**54**	**57**	**59**
Somnolence † 1			
# participants affected / at risk	**36/573 (6.28%)**	**32/543 (5.89%)**	**15/561 (2.67%)**
# events	**54**	**49**	**26**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.0

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:** The sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the sponsor as confidential must be deleted prior to submission.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
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Ho AP, Dahlöf CG, Silberstein SD, Saper JR, Ashina M, Kost JT, Froman S, Leibensperger H, Lines CR, Ho TW. Randomized, controlled trial of telcagepant over four migraine attacks. Cephalalgia. 2010 Dec;30(12):1443-57. doi: 10.1177/0333102410370878. Epub 2010 Jun 8.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00483704 History of Changes
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Health Authority:	United States: Food and Drug Administration

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