



Clinical trial results:

A Phase 1, Open-Label, Single-Dose Pharmacokinetic Study of Lasmiditan in Pediatric Patients With Migraine

Summary

EudraCT number	2019-002603-17
Trial protocol	Outside EU/EEA
Global end of trial date	24 February 2020

Results information

Result version number	v1 (current)
This version publication date	30 August 2020
First version publication date	30 August 2020

Trial information

Trial identification

Sponsor protocol code	H8H-MC-LAHX
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03988088
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16932

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-002166-PIP01-17
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 February 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the study is to measure the levels of lasmiditan in the body of children aged 6 to 17 with migraine. The study also will also examine the safety and tolerability of lasmiditan in children aged 6 to 17 with migraine.

The study will last about 6 weeks, and includes 4 visits.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 July 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 10
Country: Number of subjects enrolled	Japan: 8
Worldwide total number of subjects	18
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	12
Adolescents (12-17 years)	6
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

No Text Available

Period 1

Period 1 title	Single-Dose Pharmacokinetic Study
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
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Arm title	100 mg Lasmiditan
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Arm description:

Participants with lower body weight (15 to ≤ 40 kilograms (kg)) received single oral dose of 100 mg Lasmiditan.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	
Other name	LY573144
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received single oral dose of 100 mg Lasmiditan.

Arm title	200 mg Lasmiditan
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Arm description:

Participants with higher body weight (>40 to ≤ 55 kg) received single oral dose of 200 mg Lasmiditan.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	
Other name	LY573144
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received single oral dose of 200 mg Lasmiditan.

Number of subjects in period 1	100 mg Lasmiditan	200 mg Lasmiditan
Started	11	7
Completed	11	6
Not completed	0	1
Adverse event, non-fatal	-	1

Period 2	
Period 2 title	Open-Label Addendum
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	50 mg Lasmiditan-Addendum

Arm description:

Participants with lower body weight (15 to ≤40 kg) received single oral dose of 50 mg Lasmiditan.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	
Other name	LY573144
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received single oral dose of 50 mg Lasmiditan.

Arm title	100 mg Lasmiditan-Addendum
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Arm description:

Participants with higher body weight (>40 to ≤55 kg) received single oral dose of 100 mg Lasmiditan.

Arm type	Experimental
Investigational medicinal product name	Lasmiditan
Investigational medicinal product code	
Other name	LY573144
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received single oral dose of 100 mg Lasmiditan.

Number of subjects in period 2^[1]	50 mg Lasmiditan-Addendum	100 mg Lasmiditan-Addendum
Started	2	2
Completed	1	2
Not completed	1	0
Lost to follow-up	1	-

Notes:

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

Justification: The US participants had the option to enter this optional 3-month open-label extension addendum.

Baseline characteristics

Reporting groups

Reporting group title	100 mg Lasmiditan
Reporting group description:	
Participants with lower body weight (15 to ≤40 kilograms (kg)) received single oral dose of 100 mg Lasmiditan.	
Reporting group title	200 mg Lasmiditan
Reporting group description:	
Participants with higher body weight (>40 to ≤55 kg) received single oral dose of 200 mg Lasmiditan.	

Reporting group values	100 mg Lasmiditan	200 mg Lasmiditan	Total
Number of subjects	11	7	18
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	9.09	14.00	
standard deviation	± 2.02	± 2.65	-
Gender categorical			
Units: Subjects			
Female	6	6	12
Male	5	1	6
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	1	2
Not Hispanic or Latino	5	3	8
Unknown or Not Reported	5	3	8
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	5	3	8
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	1	6
White	1	3	4
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment			

Units: Subjects			
United States	6	4	10
Japan	5	3	8

End points

End points reporting groups

Reporting group title	100 mg Lasmiditan
Reporting group description: Participants with lower body weight (15 to ≤40 kilograms (kg)) received single oral dose of 100 mg Lasmiditan.	
Reporting group title	200 mg Lasmiditan
Reporting group description: Participants with higher body weight (>40 to ≤55 kg) received single oral dose of 200 mg Lasmiditan.	
Reporting group title	50 mg Lasmiditan-Addendum
Reporting group description: Participants with lower body weight (15 to ≤40 kg) received single oral dose of 50 mg Lasmiditan.	
Reporting group title	100 mg Lasmiditan-Addendum
Reporting group description: Participants with higher body weight (>40 to ≤55 kg) received single oral dose of 100 mg Lasmiditan.	

Primary: Pharmacokinetics (PK): Maximum Observed Drug Concentration (C_{max}) of Lasmiditan

End point title	Pharmacokinetics (PK): Maximum Observed Drug Concentration (C _{max}) of Lasmiditan ^[1]
End point description: Pharmacokinetics (PK): Maximum Observed Drug Concentration (C _{max}) of Lasmiditan.	
Analysis Population Description: All randomized participants who received at least one dose of study drug and had evaluable PK data.	
End point type	Primary
End point timeframe: 0.5, 1, 1.5, 2, 3, 4, 8, 12 and 24 hours postdose	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: No inferential statistics were planned for this endpoint.	

End point values	100 mg Lasmiditan	200 mg Lasmiditan		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	362 (± 46.7)	426 (± 43.5)		

Statistical analyses

No statistical analyses for this end point

Primary: PK: Area Under the Concentration-Versus-Time Curve (AUC) from Time Zero to Infinity (AUC_[0-∞]) of Lasmiditan

End point title	PK: Area Under the Concentration-Versus-Time Curve (AUC) from Time Zero to Infinity (AUC[0-∞]) of Lasmiditan ^[2]
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End point description:

PK: Area Under the Concentration-Versus-Time Curve (AUC) from Time Zero to Infinity (AUC[0-∞]) of Lasmiditan.

Analysis Population Description: All randomized participants who received at least one dose of study drug and had evaluable PK data.

End point type	Primary
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End point timeframe:

0.5, 1, 1.5, 2, 3, 4, 8, 12 and 24 hours postdose

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No inferential statistics were planned for this endpoint.

End point values	100 mg Lasmiditan	200 mg Lasmiditan		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	6		
Units: nanograms*hours per milliliter(ng*hr/mL)				
geometric mean (geometric coefficient of variation)	2050 (± 38.4)	2590 (± 13.7)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

H8H-MC-LAHX

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

Reporting group title	100 mg Lasmiditan
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Reporting group description: -

Reporting group title	200 mg Lasmiditan
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Reporting group description: -

Reporting group title	50 mg Lasmiditan-Addendum
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Reporting group description: -

Reporting group title	100 mg Lasmiditan-Addendum
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Reporting group description: -

Serious adverse events	100 mg Lasmiditan	200 mg Lasmiditan	50 mg Lasmiditan-Addendum
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	0 / 7 (0.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	100 mg Lasmiditan-Addendum		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	100 mg Lasmiditan	200 mg Lasmiditan	50 mg Lasmiditan-Addendum
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 11 (27.27%)	5 / 7 (71.43%)	0 / 2 (0.00%)
Nervous system disorders			
ataxia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 11 (0.00%)	2 / 7 (28.57%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
disturbance in attention			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
dizziness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 11 (9.09%)	4 / 7 (57.14%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
somnolence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 11 (18.18%)	1 / 7 (14.29%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 11 (0.00%)	3 / 7 (42.86%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Eye disorders			
lacrimation increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 11 (0.00%)	1 / 7 (14.29%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			

nausea alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 7 (14.29%) 1	0 / 2 (0.00%) 0
Psychiatric disorders confusional state alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 7 (14.29%) 1	0 / 2 (0.00%) 0
irritability alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 7 (14.29%) 1	0 / 2 (0.00%) 0

Non-serious adverse events	100 mg Lasmiditan-Addendum		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)		
Nervous system disorders ataxia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
disturbance in attention alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
dizziness alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
somnolence alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
General disorders and administration site conditions			

<p>asthenia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>fatigue</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>1 / 2 (50.00%)</p> <p>occurrences (all)</p> <p>2</p>			
<p>Eye disorders</p> <p>lacrimation increased</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Gastrointestinal disorders</p> <p>nausea</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Psychiatric disorders</p> <p>confusional state</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>irritability</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>0 / 2 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported