



Clinical trial results:

Multi-center, single-arm, open-label study in patients with Insomnia Disorder to validate the Insomnia Daytime Symptoms and Impacts Questionnaire™ (IDSIQ™)

Summary

EudraCT number	2016-004259-59
Trial protocol	DE
Global end of trial date	12 June 2017

Results information

Result version number	v1
This version publication date	28 June 2018
First version publication date	28 June 2018

Trial information

Trial identification

Sponsor protocol code	AC-078A203
-----------------------	------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03056053
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Actelion Pharmaceuticals Ltd
Sponsor organisation address	Hegenheimermattweg 95, Allschwil, Switzerland, 4123
Public contact	Clinical Trials Disclosure Desk, Idorsia Pharmaceuticals Ltd, clinical-trials-disclosure@idorsia.com
Scientific contact	Clinical Trials Disclosure Desk, Idorsia Pharmaceuticals Ltd, clinical-trials-disclosure@idorsia.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
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	27 June 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 April 2017
Global end of trial reached?	Yes
Global end of trial date	12 June 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main study objective was to assess the content validity and the psychometric characteristics of the IDSIQ™ and evaluate its appropriateness for use in the population of patients with insomnia disorder.

Protection of trial subjects:

An Independent Ethics Committee (IEC) or Institutional Review Board (IRB), i.e., a review panel that was responsible for ensuring the protection of the rights, safety and wellbeing of human subjects involved in a clinical investigation.

Sponsor personnel and the investigators ensured that the study was conducted in full compliance with ICH-Good Clinical Practice (GCP) Guidelines, the principles of the "Declaration of Helsinki", and with the laws and regulations of the countries in which the study was conducted.

Prior to any study procedure and after adequate explanation of the aims, methods, objectives, and potential hazards of the study, written informed consent was obtained from each participating subject. Subjects could voluntarily withdraw from the study without justification for any reason at any time.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 January 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 58
Country: Number of subjects enrolled	Germany: 56
Worldwide total number of subjects	114
EEA total number of subjects	56

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)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	103
From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The screening period lasted at least 14 days, from signature of informed consent at Visit 1 (Day -14) up to subject enrollment at Visit 2.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Zolpidem
-----------	----------

Arm description:

Treatment with open-label zolpidem according to prescription.

Arm type	Reference treatment
Investigational medicinal product name	Zolpidem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Commercially available zolpidem (5 or 10 mg) was administered orally once daily during the treatment period following prescribing information from each country participating in the trial (Germany and the US).

Number of subjects in period 1	Zolpidem
Started	114
Completed	112
Not completed	2
Consent withdrawn by subject	1
Adverse event, non-fatal	1

Baseline characteristics

Reporting groups

Reporting group title	Overall study
-----------------------	---------------

Reporting group description: -

Reporting group values	Overall study	Total	
Number of subjects	114	114	
Age categorical			
Units: Subjects			
Age continuous			
Full analysis set.			
Units: years			
median	53		
full range (min-max)	19 to 74	-	
Gender categorical			
Full analysis set.			
Units: Subjects			
Female	74	74	
Male	40	40	

End points

End points reporting groups

Reporting group title	Zolpidem
Reporting group description:	
Treatment with open-label zolpidem according to prescription.	

Primary: IDSIQ™ Total Score-Change from Day 1 to Day 14/15

End point title	IDSIQ™ Total Score-Change from Day 1 to Day 14/15 ^[1]
-----------------	--

End point description:

NOTE: The primary study objective was to validate a new scale. The endpoints were the items of the IDSIQ™.

The Attachment provided below describes the Conceptual Framework of the study (Figure 1) and the Responsiveness of the IDSIQ™ (Total Score) from Day 1 to Day 14/15 (Table 1).

IDSIQ™ Total Score (Weekly Average); IDSIQ™ = Insomnia Daytime Symptoms and Impacts Questionnaire™

End point type	Primary
----------------	---------

End point timeframe:

Day 1 to Day 14/15

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 statistical analysis was planned for this endpoint.

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: Score				
arithmetic mean (standard deviation)	-26.60 (± 22.802)			

Attachments (see zip file)	ACT-541468 - AC-078A203_Attachment/ACT-541468 - AC-
-----------------------------------	---

Statistical analyses

No statistical analyses for this end point

Other pre-specified: IDSIQ™ Alert/Cognition Domain_Change from Day 1 to Day 14/15

End point title	IDSIQ™ Alert/Cognition Domain_Change from Day 1 to Day 14/15
-----------------	--

End point description:

End point type	Other pre-specified
----------------	---------------------

End point timeframe:

Day 1 to Day 14/15

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: Score				
arithmetic mean (standard deviation)	-11.80 (\pm 10.741)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: IDSIQ™ Mood Domain_Change from Day 1 to Day 14/15

End point title	IDSIQ™ Mood Domain_Change from Day 1 to Day 14/15
-----------------	---

End point description:

End point type	Other pre-specified
----------------	---------------------

End point timeframe:

Day 1 to Day 14/15

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: Score				
arithmetic mean (standard deviation)	-8.42 (\pm 7.331)			

Statistical analyses

No statistical analyses for this end point

Other pre-specified: IDSIQ™ Sleepiness Domain_Change from Day 1 to Day 14/15

End point title	IDSIQ™ Sleepiness Domain_Change from Day 1 to Day 14/15
-----------------	---

End point description:

IDSIQ™ Sleepiness Domain (Weekly Average); IDSIQ™ = Insomnia Daytime Symptoms and Impacts Questionnaire™

End point type	Other pre-specified
----------------	---------------------

End point timeframe:

Day 1 to Day 14/15

End point values	Zolpidem			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: Score				
arithmetic mean (standard deviation)	-6.38 (± 5.815)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from the Screening Start (Day -14) to the Safety Follow-up (Day 45).
Below, data are reported for treatment-emergent adverse events (TEAEs).

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Zolpidem
-----------------------	----------

Reporting group description:

Zolpidem

Serious adverse events	Zolpidem		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 114 (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	Zolpidem		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 114 (10.53%)		
Nervous system disorders			
Coordination abnormal			
subjects affected / exposed	1 / 114 (0.88%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	1 / 114 (0.88%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	9 / 114 (7.89%)		
occurrences (all)	9		
Memory impairment			

subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		
Paraesthesia subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		
Somnolence subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		
General disorders and administration site conditions			
Crying subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		
Fatigue subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		
Eye disorders			
Blepharospasm subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		
Gastrointestinal disorders			
Flatulence subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		
Nausea subjects affected / exposed occurrences (all)	2 / 114 (1.75%) 2		
Tongue coated subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		
Vomiting subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		
Psychiatric disorders			
Mood swings subjects affected / exposed occurrences (all)	1 / 114 (0.88%) 1		

Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 114 (0.88%)		
occurrences (all)	1		

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