Clinical trial results:
A Local, Multicentre, Open Label Access Study, To Provide Sildenafil citrate Therapy For Subjects Who Completed A1481156 Study And Are Judged By The Investigator To Derive Clinical Benefit From Continued Treatment With Sildenafil citrate For Subjects In India

Summary

EudraCT number	2015-002238-37
Trial protocol	Outside EU/EEA
Global end of trial date	26 August 2014

Results information

Result version number	v1 (current)
This version publication date	15 March 2016
First version publication date	16 July 2015

Trial information

Trial identification

Sponsor protocol code	A1481304

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01582438
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 January 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 August 2014
Global end of trial reached?	Yes
Global end of trial date	26 August 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To provide Sildenafil citrate therapy to the paediatric subjects who had completed Study A1481156 for the treatment of PAH in India and were judged by the Investigator to derive clinical benefit from continued treatment with Sildenafil citrate citrate. The study medication was to be supplied as long as the Investigator felt that the subject continued to derive benefit from the treatment.

Protection of trial subjects:

This study was designed and monitored in accordance with Pfizer's and the CRO’s standard operating procedures (SOPs), which comply with the ethical principles of Good Clinical Practice (GCP) as required by the major regulatory authorities, and in accordance with the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 November 2012
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	India: 4
Worldwide total number of subjects	4
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)	0
Adolescents (12-17 years)	2
Adults (18-64 years)	2
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total 4 subjects were enrolled in single site in India. Subjects who had completed A1481156 were enrolled.

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	Sildenafil citrate

Arm description:

Paediatric subjects who completed Study A1481156 received Sildenafil citrate as assigned by the investigator for the treatment of pulmonary arterial hypertension up to 21 months.

Arm type	Expanded access
Investigational medicinal product name	Sildenafil citrate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Paediatric subjects were administered with Sildenafil citrate 20 milligram (mg) tablets for children with body weight greater than (>) 20 kilogram (kg), and 10 mg for children with body weight less than or equal to <=20 kg, thrice daily up to 21 months.

Number of subjects in period 1	Sildenafil citrate
Started	4
Completed	4

Baseline characteristics

Reporting groups	
Reporting group title	Sildenafil citrate
Reporting group description:	
Paediatric subjects who completed Study A1481156 received Sildenafil citrate as assigned by the investigator for the treatment of pulmonary arterial hypertension up to 21 months.	

Reporting group values	Sildenafil citrate	Total	
Number of subjects	4	4	
Age categorical Units: Subjects			
Adolescents (12-17 years)	2	2	
Adults (18-64 years)	2	2	
Gender categorical Units: Subjects			
Female	3	3	
Male	1	1	

End points

End points reporting groups

Reporting group title	Sildenafil citrate

Reporting group description:

Paediatric subjects who completed Study A1481156 received Sildenafil citrate as assigned by the investigator for the treatment of pulmonary arterial hypertension up to 21 months.

Primary: Subjects With Clinical Benefit on Usage of Continued Sildenafil Citrate

End point title	Subjects With Clinical Benefit on Usage of Continued Sildenafil Citrate[1]

End point description:

Sildenafil citrate therapy was provided to paediatric subjects for the treatment of PAH and were judged by the investigator to derive clinical benefit from continued treatment with the study drug. It was to be supplied for the treatment of PAH as long as the investigator felt that the subject continued to derive benefits from the treatment.

End point type	Primary

End point timeframe:

Up to 21 months

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 performed for this study.

End point values	Sildenafil citrate			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: subjects				
number (not applicable)				

Notes:

[2] - No efficacy analysis was performed for this study.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 21 months

Adverse event reporting additional description:

Same event may appear as both an adverse event and a serious adverse event. However, what is presented are distinct events. An event may be categorized as serious in one subject and as nonserious in another subject, or one subject may have experienced both the events. Version was not captured, here 0.0 is mentioned for dictionary version.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0.0

Reporting groups

Reporting group title	Sildenafil citrate

Reporting group description:

Paediatric subjects who completed Study A1481156 received Sildenafil citrate as assigned by the investigator for the treatment of pulmonary arterial hypertension up to 21 months.

Serious adverse events	Sildenafil citrate		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Infections and infestations			
Lower respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Sildenafil citrate		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Intermittent headache			

subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 4 (50.00%)		
occurrences (all)	2		
Rhinitis allergic			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 4 (25.00%)		
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