Clinical trial results:
Multinational, randomized, double blind, double dummy, pharmacokinetic study of telithromycin oral suspension (25 mg/kg once daily for 7-10 days), with secondary assessments of safety relative to azithromycin oral suspension (10 mg/kg once daily for 1 day followed by 5 mg/kg once daily for 4 days) in children with mild to moderate community-acquired pneumonia

Summary

EudraCT number	2014-002867-13
Trial protocol	Outside EU/EEA
Global end of trial date	13 September 2007

Results information

Result version number	v1 (current)
This version publication date	23 May 2016
First version publication date	14 June 2015

Trial information

Trial identification

Sponsor protocol code	POP6135,HMR3647B/3005

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Sanofi U.S Services Inc.
Sponsor organisation address	55 Corporate Drive Bridgewater,, New Jersey,, United States, 08807
Public contact	Trial Transparency Team, Sanofi Aventis Recherche & Developpement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Aventis Recherche & Developpement, Contact-US@sanofi.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	13 September 2007
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 September 2007
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the steady state pharmacokinetics of telithromycin oral suspension (25 mg/kg once a day for 7-10 days), in children 6 months to less than 13 years of age (<13) with community acquired pneumonia (CAP).

Protection of trial subjects:

The study was conducted by investigators experienced in the treatment of pediatric subjects. The parent(s) or guardian(s) as well as the children were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time. In addition to the consent form for the parent(s)/guardian(s), an assent form in childappropriate language was provided and explained to the child. Repeated invasive procedures were minimized. The number of blood samples as well as the amount of blood drawn were adjusted according to age and weight. A topical anesthesia may have been used to minimize distress and discomfort.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 May 2006
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: 1
Worldwide total number of subjects	1
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)	1
Adolescents (12-17 years)	0

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at one site in the United States. Enrolment was terminated after only one subject was recruited.

Pre-assignment

Screening details:

The subject was randomized in theTelithromycin arm. And so no subject was randomized in the Azithromycin arm (active comparator).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Assessor

Arms

Arm title	Telithromycin

Arm description:

Telithromycin for 7-10 days.

Arm type	Experimental
Investigational medicinal product name	Telithromycin
Investigational medicinal product code	HMR3647B
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

25 mg/kg once daily.

Investigational medicinal product name	Placebo (for Azithromycin)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Placebo (for azithromycin) once daily.

Number of subjects in period 1	Telithromycin
Started	1
Treated	1
Completed	1

Baseline characteristics

Reporting groups	
Reporting group title	Telithromycin
Reporting group description:	
Telithromycin for 7-10 days.	

Reporting group values	Telithromycin	Total	
Number of subjects	1	1	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	1	1	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	0	0	
Male	1	1	

End points

End points reporting groups

Reporting group title	Telithromycin
Reporting group description: Telithromycin for 7-10 days.	

Primary: Telithromycin plasma concentration

End point title	Telithromycin plasma concentration[1]
End point description:	

End point type	Primary
End point timeframe: (Day 6-10) end of treatment	

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 analyze was performed because of the early termination after one subject was enrolled.

End point values	Telithromycin			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: ng/mL				
arithmetic mean (standard deviation)	()			

Notes:

[2] - Analyze not performed because of the early termination after one subject was enrolled.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with adverse events of special interest

End point title	Number of subjects with adverse events of special interest
End point description:	

End point type	Secondary
End point timeframe: Up to Day 17-24 post-therapy	

End point values	Telithromycin			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Subjects				
Cardiac events	0			
Hepatic events	0			
Visual disturbances	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All Adverse Events (AE) were collected from signature of the informed consent form up to the final visit (day 17 to 24) regardless of seriousness or relationship to investigational product. Analysis was performed on safety population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Reporting groups

Reporting group title	Telithromycin

Reporting group description: -

Serious adverse events	Telithromycin		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (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	Telithromycin		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No adverse event reported in this project

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 March 2006	This amendment has two objectives: 1. Include exclusion criteria for subjects at risk for respiratory distress. 2. To include the collection of sputum for Gram stain and culture and information about handling of microbiology specimens. The adjustments are supported by a request from the FDA.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
01 June 2006	In June 2006, the Sponsor voluntarily paused enrollment in pediatric clinical trials with no subsequent recruitment of subjects. On 13 September 2007, the Sponsor informed the study sites that the trial was terminated.	-

Notes:

Limitations and caveats

None reported