Clinical trial results:
A Multicenter, Randomized, Double-blind, Placebo- and Active-Controlled Study Comparing the Safety and Analgesic Efficacy of ABT-110 to Placebo in Subjects with Chronic Low Back Pain

Summary

EudraCT number	2011-002143-95
Trial protocol	NO PL IT FI
Global end of trial date	19 December 2012

Results information

Result version number	v1 (current)
This version publication date	20 April 2016
First version publication date	09 July 2015

Trial information

Trial identification

Sponsor protocol code	M12-141

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6 4XE
Public contact	Global Medical Information, AbbVie, 001 800-633-9110,
Scientific contact	Jerry Hall, MD, AbbVie, jerry.hall@abbvie.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	19 December 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 December 2012
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective for this study is to compare the safety, tolerability and the analgesic efficacy of ABT-110 administered subcutaneously (SC) once every 8 weeks (q8w) for a total of two doses to placebo in subjects with chronic low back pain (CLBP).
One subject was enrolled into the study prior to the study being prematurely discontinued by the Sponsor based on a strategic business decision. No statistical, pharmacokinetic or pharmacogenetic analyses were performed. Safety data are provided for the 1 subject who received placebo.

Protection of trial subjects:

Subject and/or legal guardian read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 November 2012
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	South Africa: 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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Approximately 330 subjects were planned to be enrolled. One subject was enrolled into the study prior to the study being prematurely discontinued by the Sponsor based on a strategic business decision.

Pre-assignment

Screening details:

One subject was enrolled and randomized to receive placebo. No subjects were randomized to ABT-110 (planned doses of 5, 10, 20, and 30 mg ABT-110) or naproxen (planned dose of 500 mg).

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, Monitor, Carer, Assessor

Arms

Arm title	Placebo

Arm description:

Placebo for ABT-110 by subcutaneous (SC) injection every 8 weeks (q8w) for a total of 2 doses, and placebo for naproxen by capsule orally once daily (BID) for 16 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo for ABT-110
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo for ABT-110 administered by subcutaneous injection

Investigational medicinal product name	Placebo for naproxen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Placebo for naproxen administered orally as capsule

Number of subjects in period 1	Placebo
Started	1
Completed	0
Not completed	1
Early termination of study by Sponsor	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Placebo for ABT-110 by subcutaneous (SC) injection every 8 weeks (q8w) for a total of 2 doses, and placebo for naproxen by capsule orally once daily (BID) for 16 weeks.

Primary: Change from Baseline to Week 16 in Subject's Assessment of Chronic Lower Back Pain (CLPB) Intensity by 100 mm Visual Analog Scale (VAS)

End point title	Change from Baseline to Week 16 in Subject's Assessment of Chronic Lower Back Pain (CLPB) Intensity by 100 mm Visual Analog Scale (VAS)[1]

End point description:

The change from the baseline visit to Week 16 in subject's assessment of pain intensity, assessed using the CLBP Intensity VAS (0 mm = No Pain and 100 mm = Worst Pain Imaginable).

End point type	Primary

End point timeframe:

Baseline Visit (prior to dosing on day of initial study drug administration) to Week 16

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: Not analyzed due to study termination

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

Notes:

[2] - not analyzed due to study termination

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse events were collected from the time of study drug administration through follow up at Week 20 (20 weeks); serious adverse events were collected from the time that informed consent was obtained (24 weeks).

Adverse event reporting additional description:

All adverse events were collected whether solicited or spontaneously reported by the subject.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.0

Reporting groups

Reporting group title	Placebo

Reporting group description:

Placebo for ABT-110 by subcutaneous (SC) injection every 8 weeks (q8w) for a total of 2 doses, and placebo for naproxen by capsule orally once daily (BID).

Serious adverse events	Placebo		
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	Placebo		
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: The study was terminated. No adverse events were reported for the 1 subject enrolled.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 April 2012	To change the low end of the tested dose range from 3 mg to 5 mg ABT-110 and to decrease the upper dose limit from 40 mg to 30 mg ABT-110; add additional post study drug administration monitoring; update safety and pharmacokinetic information because data was no longer preliminary; add description of study's anticipated benefits and risks; decrease the sample size from 390 (65 per arm) to 330 (55 per arm); revise inclusion and exclusion criteria to clarify criterion for duration of history of chronic low back pain and therapeutic dosing, add upper limit for BMI, increase threshold score for Mini-Mental Status Examination score, and exclude subjects with clinically significant allergy to medications used in study, history of rapidly progressive osteoarthritis, scoliosis surgery, osteoarthritis, or juvenile rheumatoid arthritis, or coronary artery bypass graft; provide additional detail regarding exclusionary treatment with corticosteroids, prohibited medications, or prior biologic therapy; clarify study procedures; clarify timing of efficacy measures; clarify role of the independent data monitoring committee; update adverse event definitions and management; and add interim efficacy and pharmacokinetic analyses.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported