Clinical trial results:
A multi-center, randomized, double-blind, placebo-controlled Phase IIa trial to compare the safety of ABX464 given at a fixed dose to placebo in fully controlled HIV infected patients treated with boosted protease inhibitor treatment (darunavir/ritonavir or darunavir/cobicistat).

Summary

EudraCT number	2015-004195-30
Trial protocol	BE ES FR
Global end of trial date	11 January 2018

Results information

Result version number	v1 (current)
This version publication date	01 July 2022
First version publication date	01 July 2022

Trial information

Trial identification

Sponsor protocol code	ABX464-004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02735863
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Abivax
Sponsor organisation address	5 rue de la Baume, Paris, France, 75008
Public contact	Head of Clinical Operations, Abivax, +33 01 53 83 09 61, Paul.Gineste@abivax.com
Scientific contact	Chief Medical Officer , Abivax, + 33 01 53 83 09 61, Sophie.biguenet@abivax.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	11 January 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 August 2017
Global end of trial reached?	Yes
Global end of trial date	11 January 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety of ABX464 versus placebo when administered on top of darunavir/ritonavir or darunavir/cobicistat monotherapy.

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form (ICF).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 May 2016
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	Spain: 11
Country: Number of subjects enrolled	Belgium: 17
Country: Number of subjects enrolled	France: 2
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Eligible patients were treated with DRV/RTV or DRV/COBI as monotherapy for at least 8 weeks prior to baseline.
Patients were fully suppressed (<50 copies/mL) for at least 6 months prior to enrolment

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	ABX464 50mg

Arm description:

ABX464 50mg with darunavir + ritonavir (DRV/RTV) or darunavir + cobicistat (DRV/COBI)

Arm type	Experimental
Investigational medicinal product name	ABX464
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

ABX464 50mg - oral route - in fed condition (regular breakfast) with 240 mL of water.

Arm title	ABX464 150mg

Arm description:

ABX464 150mg with darunavir + ritonavir (DRV/RTV) or darunavir + cobicistat (DRV/COBI)

Arm type	Experimental
Investigational medicinal product name	ABX464
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

ABX464 150mg - oral route - in fed condition (regular breakfast) with 240 mL of water.

Arm title	Placebo

Arm description:

Placebo with darunavir + ritonavir (DRV/RTV) or darunavir + cobicistat (DRV/COBI)

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

Dosage and administration details:
Placebo - oral route - dosed in fed condition (regular breakfast) with 240 mL of water.

Number of subjects in period 1	ABX464 50mg	ABX464 150mg	Placebo
Started	6	16	8
Completed	5	14	7
Not completed	1	2	1
Physician decision	-	1	1
Adverse event, non-fatal	-	1	-
Lost to follow-up	1	-	-

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	30	30	
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)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	30	30	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	1	1	
Male	29	29	

End points

End points reporting groups

Reporting group title	ABX464 50mg
Reporting group description:	
ABX464 50mg with darunavir + ritonavir (DRV/RTV) or darunavir + cobicistat (DRV/COBI)	
Reporting group title	ABX464 150mg
Reporting group description:	
ABX464 150mg with darunavir + ritonavir (DRV/RTV) or darunavir + cobicistat (DRV/COBI)	
Reporting group title	Placebo
Reporting group description:	
Placebo with darunavir + ritonavir (DRV/RTV) or darunavir + cobicistat (DRV/COBI)	

Primary: Frequency of Adverse Reactions tabulated (counts and percents) by goup and dose

End point title	Frequency of Adverse Reactions tabulated (counts and percents) by goup and dose[1]
End point description:	
End point type	Primary
End point timeframe:	
Up to 4 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 for this endpoint

End point values	ABX464 50mg	ABX464 150mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	16	8	
Units: 30	5	15	7	

Attachments (see zip file)	Table - Summary of AE.docx

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Viral Rebound

End point title	Time to Viral Rebound
End point description:	
End point type	Secondary
End point timeframe:	
Up to 3 months	

End point values	ABX464 50mg	ABX464 150mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	16	8	
Units: Days				
arithmetic mean (standard deviation)	17.2 (± 3.4)	14.4 (± 7.4)	14.4 (± 7.3)	

Statistical analyses

Statistical analysis title	Secondary endpoint statical analysis
Comparison groups	ABX464 50mg v ABX464 150mg v Placebo
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 5352
Method	Logrank

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From baseline up to 112 days	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0
Reporting groups	
Reporting group title	ABX464 50mg
Reporting group description: -	
Reporting group title	ABX464 150mg
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Serious adverse events	ABX464 50mg	ABX464 150mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 16 (0.00%)	0 / 8 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	ABX464 50mg	ABX464 150mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	15 / 16 (93.75%)	3 / 8 (37.50%)
Investigations			
C-reactive Protein Increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 16 (6.25%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 16 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Scar			

subjects affected / exposed	1 / 6 (16.67%)	0 / 16 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 6 (33.33%)	5 / 16 (31.25%)	0 / 8 (0.00%)
occurrences (all)	2	7	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	3 / 16 (18.75%)	0 / 8 (0.00%)
occurrences (all)	0	5	0
Influenza Like Illness			
subjects affected / exposed	1 / 6 (16.67%)	1 / 16 (6.25%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 6 (0.00%)	3 / 16 (18.75%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Abdominal Pain Upper			
subjects affected / exposed	0 / 6 (0.00%)	4 / 16 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	5	0
Diarrhea			
subjects affected / exposed	1 / 6 (16.67%)	3 / 16 (18.75%)	0 / 8 (0.00%)
occurrences (all)	2	5	0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	2 / 16 (12.50%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 16 (12.50%)	1 / 8 (12.50%)
occurrences (all)	0	3	1
Back Pain			
subjects affected / exposed	2 / 6 (33.33%)	5 / 16 (31.25%)	0 / 8 (0.00%)
occurrences (all)	2	6	0
Infections and infestations			
Nasopharyngitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 16 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 16 (6.25%)	1 / 8 (12.50%)
occurrences (all)	0	1	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 April 2016	Main changes: adjustment in the secondary objectives; adjustment in inclusion criteria; addition of prohibited prior or concomitant treatments; Some Fommow up visits have been implemented; modification in the study design
11 July 2016	main changes: addition of a potentially dose; sample size section has been updated
07 November 2016	Main changes: Enhancement of the DSMB oversight; Update of the Non-clinical background information

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported