



Clinical trial results:

A follow-up Phase IIa study to evaluate the long-term safety and efficacy profile of ABX464 given at 50 mg once daily in subjects with Moderate to Severe Active Ulcerative Colitis.

Summary

EudraCT number	2017-003284-35
Trial protocol	BE HU PL ES
Global end of trial date	15 August 2022

Results information

Result version number	v1 (current)
This version publication date	20 August 2025
First version publication date	20 August 2025

Trial information

Trial identification

Sponsor protocol code	ABX464-102
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Abivax
Sponsor organisation address	7-11 Blvd Haussmann, Paris, France, 75009
Public contact	External Communication, Abivax, +33 1 53 83 09 63, info@abivax.com
Scientific contact	External Communication, Abivax, +33 1 53 83 09 63, info@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	15 August 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 July 2022
Global end of trial reached?	Yes
Global end of trial date	15 August 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to evaluate the long-term safety of ABX464 given at 50 mg once daily in subjects with Moderate to Severe Active Ulcerative Colitis.

Protection of trial subjects:

In the informed consent, subjects were asked to report all experienced adverse events to their study doctor.

In case health problems occurred, the study doctor asked subject to return to their facility for an unscheduled visit.

If it was not possible to contact the study doctor or the site, subjects were asked to contact any healthcare professional or other competent person.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 January 2018
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	Poland: 10
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Hungary: 9
Worldwide total number of subjects	22
EEA total number of subjects	22

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)	20

From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

recruitment in Belgium: from 26Jan2018 to 23Apr2018

recruitment in Poland: from 24Apr2018 to 03Jul2018

recruitment in Hungary: from 09Apr2018 to 05Jul2018

Pre-assignment

Screening details:

Subjects were previously enrolled in the ABX464-101 clinical study (induction study) and were willing to continue their treatment

Period 1

Period 1 title	overall study period (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	obefazimod 50mg
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Arm description:

All subjects receive ABX464 at 50 mg o.d for an overall period of 48 months.

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

Dosage and administration details:

The ABX464 investigational medicinal product (IMP) is a hard gelatin capsule intended for oral administration. Subjects are dosed with a daily dose of 50 mg that is 1 capsule every day.

Number of subjects in period 1	obefazimod 50mg
Started	22
Completed	11
Not completed	11
sponsor decision	4
Consent withdrawn by subject	3
Physician decision	1
Adverse event, non-fatal	2
worsening of UC	1

Baseline characteristics

Reporting groups

Reporting group title	obefazimod 50mg
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Reporting group description:

All subjects receive ABX464 at 50 mg o.d for an overall period of 48 months.

Reporting group values	obefazimod 50mg	Total	
Number of subjects	22	22	
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)	20	20	
From 65-84 years	2	2	
85 years and over	0	0	
Age continuous			
Units: years			
geometric mean	42.4		
standard deviation	± 14.3	-	
Gender categorical			
Units: Subjects			
Female	9	9	
Male	13	13	

Subject analysis sets

Subject analysis set title	Observed Cases (OC) set
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Subject analysis set type	Safety analysis
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Subject analysis set description:

The Observed Cases (OC) Set was defined as those subjects included in the study, who had received at least one dose of the study treatment

Reporting group values	Observed Cases (OC) set		
Number of subjects	22		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	20		
From 65-84 years	2		
85 years and over	0		
Age continuous			
Units: years			
geometric mean	42.4		
standard deviation	± 14.3		
Gender categorical			
Units: Subjects			
Female	9		
Male	13		

End points

End points reporting groups

Reporting group title	obefazimod 50mg
Reporting group description: All subjects receive ABX464 at 50 mg o.d for an overall period of 48 months.	
Subject analysis set title	Observed Cases (OC) set
Subject analysis set type	Safety analysis
Subject analysis set description: The Observed Cases (OC) Set was defined as those subjects included in the study, who had received at least one dose of the study treatment	

Primary: number of treatment emergent adverse event

End point title	number of treatment emergent adverse event ^[1]
End point description: Only descriptive analysis was performed. For qualitative variable, count and percentage were presented.	
End point type	Primary
End point timeframe: 48 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: Only descriptive analysis was performed. For qualitative variable, count and percentage were presented.	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: number of adverse events	145			

Statistical analyses

No statistical analyses for this end point

Secondary: Total Mayo Score

End point title	Total Mayo Score
End point description: The change from Day 0 up to Month 48 in Total Mayo Score. total mayo score is an index and consists of 4 items: stool frequency, rectal bleeding, flexible sigmoidoscopic examination, and a physician global assessment of disease activity. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity). The total mayo score scale ranging is from 0 to 12 The change from baseline of this score is part of the clinical response definition: to get a clinical response, a reduction in Total Mayo score of at least 2 points is required. A higher (in negative) change shows a better clinical response.	
End point type	Secondary
End point timeframe: 48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: units on a scale				
arithmetic mean (standard deviation)	-3.0 (± 3.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Partial Mayo Score

End point title	Partial Mayo Score
End point description:	
The change from Day 0 up to Month 48 in Partial Mayo Score; Partial Mayo score is an index and consists of 3 items: stool frequency, rectal bleeding and a physician global assessment of disease activity. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity). The partial mayo score scale ranging is from 0 to 9. A higher (in negative) change from baseline shows a better clinical response.	
End point type	Secondary
End point timeframe:	
48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: units on a scale				
arithmetic mean (standard deviation)	-2.2 (± 2.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinical Response at Month 48

End point title	Number of Subjects With Clinical Response at Month 48
End point description:	
Clinical response was defined as: reduction in Total Mayo Score (TMS) of at least 2 points and ≥ 30 percent from baseline with an accompanying decrease in rectal bleeding sub-score of ≥ 1 point or absolute rectal bleeding sub-score of ≤ 1 point.	

End point type	Secondary
End point timeframe:	
48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: number of subjects	11			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinical Remission at Month 48

End point title	Number of Subjects With Clinical Remission at Month 48
End point description:	
Clinical remission was achieved when all the following criteria were met in the components of the Mayo clinical Score: rectal bleeding sub-score = 0 central endoscopy sub-score ≤ 1 stool frequency sub-score ≤ 1	
End point type	Secondary
End point timeframe:	
48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: number of subjects	9			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subject With Endoscopic Improvement at Month 48

End point title	Number of Subject With Endoscopic Improvement at Month 48
End point description:	
Endoscopic improvement was achieved if the Mayo central endoscopic sub-score is 0 or 1.	
End point type	Secondary
End point timeframe:	
48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: number of subjects	9			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Endoscopic Remission at Month 48

End point title	Number of Subjects With Endoscopic Remission at Month 48
End point description:	Endoscopic remission was defined as Mayo central endoscopic sub-score = 0
End point type	Secondary
End point timeframe:	48 months

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: number of subjects	6			

Statistical analyses

No statistical analyses for this end point

Secondary: Fecal Calprotection levels

End point title	Fecal Calprotection levels
End point description:	The change from Day 0 up to Month 48 in fecal calprotectin A higher (in negative) change shows a better efficacy
End point type	Secondary
End point timeframe:	48 months

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: ug/g				
arithmetic mean (standard deviation)	-299.69 (\pm 472.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: CRP levels

End point title	CRP levels
End point description: The change from Day 0 up to Month 48 in CRP levels	
End point type	Secondary
End point timeframe: 48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: mg/L				
arithmetic mean (standard deviation)	2.29 (\pm 4.82)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treatment-emergent Serious Adverse Events

End point title	Number of Treatment-emergent Serious Adverse Events
End point description: The number of incidences of treatment-emergent serious adverse events	
End point type	Secondary
End point timeframe: 48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: number of events	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treatment-emergent Adverse Events of Special Interest

End point title	Number of Treatment-emergent Adverse Events of Special Interest
End point description: The number of incidences of treatment-emergent adverse events of special interest	
End point type	Secondary
End point timeframe: 48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: number of events	15			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Adverse Events Leading to Investigational Product Discontinuation

End point title	Number of Adverse Events Leading to Investigational Product Discontinuation
End point description: The number of incidences of adverse events leading to investigational product discontinuation	
End point type	Secondary
End point timeframe: 48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: number of events	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Specific Laboratory Abnormalities

End point title	Number of Specific Laboratory Abnormalities
End point description: The number of incidences of specific laboratory abnormalities	
End point type	Secondary
End point timeframe: 48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: number of events	17			

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Quality of Life Questionnaire (SF-36 Physical Component)

End point title	SF-36 Quality of Life Questionnaire (SF-36 Physical Component)
End point description: Change from Day 0 up to 24 months in SF-36 Questionnaire scores; The SF-36 questionnaire is a self-administered questionnaire containing 36 items. It measures health on eight multi-item dimensions, covering functional status, well-being, and overall evaluation of health. These items are grouped in 2 distincts components: a physical component (SF-36 physical) and a mental component (SF-36 mental). This outcome describes the SF-36 physical component. Each item score ranging is from 0 to 100. A higher positive value in change indicate a better health status. The higher the change from baseline, the better improvement	
End point type	Secondary
End point timeframe: 48 months	

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: units on a scale				
arithmetic mean (standard deviation)	4.82 (\pm 4.23)			

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Quality of Life Questionnaire (SF-36 Mental Component)

End point title	SF-36 Quality of Life Questionnaire (SF-36 Mental Component)
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End point description:

Change from Day 0 up to 24 months in SF-36 Questionnaire scores; The SF-36 questionnaire is a self-administered questionnaire containing 36 items.

It measures health on eight multi-item dimensions, covering functional status, well-being, and overall evaluation of health.

These items are grouped in 2 distinct components: a physical component (SF-36 physical) and a mental component (SF-36 mental).

This outcome describes the SF-36 mental component. Each item score ranging is from 0 to 100. A higher positive value in change indicate a better health status. The higher the change from baseline, the better improvement

End point type	Secondary
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End point timeframe:

48 months

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: unit on a scale				
arithmetic mean (standard deviation)	6.38 (\pm 3.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Erythrocyte Sedimentation Rate (ESR) Levels

End point title	Erythrocyte Sedimentation Rate (ESR) Levels
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End point description:

The change from Day 0 up to Month 48 in ESR levels

End point type	Secondary
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End point timeframe:

48 months

End point values	Observed Cases (OC) set			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: mm/hour				
arithmetic mean (standard deviation)	2.9 (± 8.62)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

48 months

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.0
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Reporting groups

Reporting group title	Safety analysis
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Reporting group description:

The safety analysis used the Observed Cases (OC) Set defined as those subjects included in the study, who had received at least one dose of the study treatment

Serious adverse events	Safety analysis		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 22 (13.64%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign ovarian tumor			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Enteropathic spondylitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Non-serious adverse events	Safety analysis		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 22 (81.82%)		
Nervous system disorders			
headache			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	7		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	5 / 22 (22.73%)		
occurrences (all)	5		
Dyspepsia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	3		
colitis ulcerative			
subjects affected / exposed	7 / 22 (31.82%)		
occurrences (all)	11		
diarrhoea			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	10		
nausea			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
vomiting			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			

Nasal congestion subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2		
oropharyngeal pain subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2		
Musculoskeletal and connective tissue disorders arthralgia subjects affected / exposed occurrences (all)	2 / 22 (9.09%) 2		
Infections and infestations nasopharyngitis subjects affected / exposed occurrences (all)	5 / 22 (22.73%) 9		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 November 2018	Extension of overall study period from 12 months to 24 months
12 November 2019	Extension of overall study period from 24 months to 36 months
21 September 2020	Extension of overall study period from 36 months to 48 months
18 August 2021	End of study confirmation at M48 and possibility to enter a new long-term safety study (ABX464-108), addition of adverse event of special interest definition
07 February 2022	Update after investigator's brochure V7.0 release (prohibited medications, obefazimod previous clinical experience, study discontinuation criteria, safety updates), clarification of adverse event of special interest terms

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported