Clinical trial results:
A follow-up Phase 2a open-label study to evaluate the long-term safety and efficacy profile of ABX464 in patients with moderate to severe active Rheumatoid Arthritis.

Summary

EudraCT number	2019-001578-27
Trial protocol	HU BE
Global end of trial date	23 January 2023

Results information

Result version number	v1 (current)
This version publication date	23 November 2025
First version publication date	23 November 2025

Trial information

Trial identification

Sponsor protocol code	ABX464-302

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04049448
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Abivax
Sponsor organisation address	7-11 Blvd Haussmann, Paris, France, 75009
Public contact	Study Director, Abivax, +33 (0)153830963, info@abivax.com
Scientific contact	Study Director, Abivax, +33 (0)153830963, 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	06 April 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 January 2023
Global end of trial reached?	Yes
Global end of trial date	23 January 2023
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 50mg once daily in patients with moderate to severe active Rheumatoid Arthritis.

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 occured, 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	25 October 2019
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: 25
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	France: 4
Country: Number of subjects enrolled	Hungary: 6
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	29
From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment in Belgium: from 21Apr2020 to 27Apr2021
Recruitment in France: from 02Mar2020 to 01Mar2021
Recruitment in Hungary: from 07Apr2020 to 21Sep2020
Recruitment in Poland: from 25Oct2019 to 03Mar2021

Pre-assignment

Screening details:

Subjects were previously enrolled in the ABX464-301 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

Arm description:

All subjects receive ABX464 at 50 mg o.d for an overall period of 104 weeks

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	40
Completed	15
Not completed	25
Physician decision	6
Consent withdrawn by subject	5
subject's decision	4
Adverse event, non-fatal	7
worsening of rheumatoid arthritis	2
sponsor's decision	1

Baseline characteristics

Reporting groups

Reporting group title	Overall study period

Reporting group description: -

Reporting group values	Overall study period	Total	
Number of subjects	40	40	
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)	29	29	
From 65-84 years	11	11	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	57.0		
standard deviation	± 10.8	-	
Gender categorical Units: Subjects			
Female	25	25	
Male	15	15	

Subject analysis sets

Subject analysis set title	Observed Cases (OC) Set
Subject analysis set type	Safety analysis

Subject analysis set description:

all subjects who have received at least 1 dose of the study treatment. For the efficacy analysis, the denominator for each percentage was the number of subjects with non-missing observations.

Reporting group values	Observed Cases (OC) Set		
Number of subjects	40		
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)	29		
From 65-84 years	11		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	57.0		
standard deviation	± 10.8		
Gender categorical			
Units: Subjects			
Female	25		
Male	15		

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 104 weeks

Subject analysis set title	Observed Cases (OC) Set
Subject analysis set type	Safety analysis

Subject analysis set description:

all subjects who have received at least 1 dose of the study treatment. For the efficacy analysis, the denominator for each percentage was the number of subjects with non-missing observations.

Primary: Number of subjects with adverse events emerging during treatment, categorized by severity

End point title	Number of subjects with adverse events emerging during treatment, categorized by severity[1]

End point description:

End point type	Primary

End point timeframe:

up to 108 weeks (104 weeks of treatment + 4 weeks of safety period)

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: This is an open-label study. Only descriptive statistics were performed.

End point values	obefazimod 50mg	Observed Cases (OC) Set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	40	40		
Units: participants				
Grade 1	29	29		
Grade 2	24	24		
Grade 3	3	3		
Grade 4	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of patients achieving DAS28-ESR remission (DAS28 ESR < 2.6) at Week 52

End point title	Number of patients achieving DAS28-ESR remission (DAS28 ESR < 2.6) at Week 52

End point description:

The Disease Activity Score (DAS)28-Erythrocyte Sedimentation Rate (DAS28-ESR) components is a score calculated with the following formula:
DAS28-ESR = 0.56 √ (TJC28) + 0.28 √ (SJC28) + 0.70 Ln [ESR(mm/h)] + 0.014 PtGA(VAS100mm)
- o TJC28: tender/painful joint count (28),
- o SJC28: swollen joint count (28),
- o ESR: Erythrocyte Sedimentation Rate (in mm/h), and

o PtGA: patient global assessment of disease expressed as a Visual Analog Scale (VAS) from 0 to 100 mm

The DAS28-ESR remission is defined when the score is < 2.6

End point type	Secondary

End point timeframe:

At Week 52

End point values	obefazimod 50mg	Observed Cases (OC) Set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	22[2]	22[3]		
Units: participants	7	7		

Notes:

[2] - Subjects with non missing observations

[3] - Subjects with non missing observations

Statistical analyses

No statistical analyses for this end point

Secondary: Number of patients achieving DAS28-ESR remission (DAS28 ESR < 2.6) at Week 104

End point title	Number of patients achieving DAS28-ESR remission (DAS28 ESR < 2.6) at Week 104

End point description:

The Disease Activity Score (DAS)28-Erythrocyte Sedimentation Rate (DAS28-ESR) components is a score calculated with the following formula:
DAS28-ESR = 0.56 √ (TJC28) + 0.28 √ (SJC28) + 0.70 Ln [ESR(mm/h)] + 0.014 PtGA(VAS100mm)
o TJC28: tender/painful joint count (28),
o SJC28: swollen joint count (28),
o ESR: Erythrocyte Sedimentation Rate (in mm/h), and
o PtGA: patient global assessment of disease expressed as a Visual Analog Scale (VAS) from 0 to 100 mm

The DAS28-ESR remission is defined when the score is < 2.6

End point type	Secondary

End point timeframe:

At Week 104

End point values	obefazimod 50mg	Observed Cases (OC) Set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	11[4]	11[5]		
Units: participants	5	5		

Notes:

[4] - Subjects with non missing observations

[5] - Subjects with non missing observations

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: up to 108 weeks (104 weeks of treatment period + 4 weeks of safety period)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups	
Reporting group title	Safety analysis

Reporting group description: -

Serious adverse events	Safety analysis		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 40 (10.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pleurisy			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Emotional distress			

subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Safety analysis		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 40 (85.00%)		
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	3		
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	4		
Headache			
subjects affected / exposed	13 / 40 (32.50%)		
occurrences (all)	30		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Diarrhoea			
subjects affected / exposed	12 / 40 (30.00%)		
occurrences (all)	31		
Dyspepsia			

subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Nausea			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	6		
Vomiting			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Back pain			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	3		
Bursitis			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		
Rheumatoid arthritis			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	4		
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 40 (7.50%)		
occurrences (all)	3		
COVID-19			
subjects affected / exposed	5 / 40 (12.50%)		
occurrences (all)	5		
Nasopharyngitis			
subjects affected / exposed	4 / 40 (10.00%)		
occurrences (all)	4		
Oral herpes			

subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	4		
Periodontitis			
subjects affected / exposed	2 / 40 (5.00%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 September 2020	Extension of study duration (from 52 to 104 weeks)
16 August 2021	Clarifications about discontinuation criteria and adverse events of special interest
10 February 2022	Update after Investigator's Brochure V7.0 release (changes in introduction and prohibited medications)
08 June 2022	change of pharmacovigilance service provider, addition of new available preclinical data and clarification in definitions of adverse events of special interest

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported