



Clinical trial results:

A phase 2b, open-label, efficacy and safety study of ABX464 as maintenance therapy in patients with moderate to severe Ulcerative Colitis.

Summary

EudraCT number	2019-000733-39
Trial protocol	SK PL AT SI BE CZ ES HU GB FR DE IT
Global end of trial date	23 February 2023

Results information

Result version number	v1 (current)
This version publication date	19 July 2026
First version publication date	19 July 2026

Trial information

Trial identification

Sponsor protocol code	ABX464-104
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04023396
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Abivax
Sponsor organisation address	7-11 Blvd. Haussmann, Paris, France, 75009
Public contact	Clinical Operations, ABIVAX, +33 630031132, laurence.desroys@abivax.com
Scientific contact	Clinical Operations, ABIVAX, +33 630031132, laurence.desroys@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	29 March 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 February 2023
Global end of trial reached?	Yes
Global end of trial date	23 February 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to assess in all patients the long-term efficacy of ABX464 given at 50 mg QD on clinical remission at Week 48 compared to the induction study (ABX464-103) baseline (ISB).

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	13 January 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	24 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 63
Country: Number of subjects enrolled	Slovakia: 16
Country: Number of subjects enrolled	Slovenia: 3
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Austria: 7
Country: Number of subjects enrolled	Belgium: 8
Country: Number of subjects enrolled	Czechia: 12
Country: Number of subjects enrolled	France: 24
Country: Number of subjects enrolled	Germany: 9
Country: Number of subjects enrolled	Hungary: 17
Country: Number of subjects enrolled	Italy: 17
Country: Number of subjects enrolled	Ukraine: 30
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Serbia: 5
Worldwide total number of subjects	217
EEA total number of subjects	177

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)	202
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

NOT APPLICABLE

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	ABX464 50 mg
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Arm description:

All subjects will receive ABX464 administered at 50 mg o.d for an overall period of 96 weeks.

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:

All subjects will receive ABX464 administered at 50 mg o.d for an overall period of 96 weeks.

Number of subjects in period 1	ABX464 50 mg
Started	217
Completed	164
Not completed	53
Adverse event, serious fatal	1
Consent withdrawn by subject	14
Physician decision	4
Adverse event, non-fatal	16
e.g Ukraine crisis	10
Pregnancy	4
Lost to follow-up	1
Lack of efficacy	3

Baseline characteristics

Reporting groups

Reporting group title	overall trial
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Reporting group description:

All subjects will receive ABX464 administered at 50 mg o.d for an overall period of 96 weeks.

Reporting group values	overall trial	Total	
Number of subjects	217	217	
Age categorical			
Units: Subjects			
Adults (18-64 years)	202	202	
From 65-84 years	15	15	
Age continuous			
Units: years			
arithmetic mean	42.1		
standard deviation	± 13.77	-	
Gender categorical			
Units: Subjects			
Female	84	84	
Male	133	133	

Subject analysis sets

Subject analysis set title	Full analysis set [FAS]
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Subject analysis set type	Full analysis
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Subject analysis set description:

The FAS included all patients in the study who received at least one dose of the study treatment, and who had BOLS (Baseline of the open-label study) data for at least one efficacy variable.

Subject analysis set title	Sustained endoscopic improvement at Week 8 of induction study
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

At Week 8 of the induction study, endoscopic improvement was achieved by 70 patients

Subject analysis set title	Sustained endoscopic remission at Week 8 of induction study
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

number of patients who achieved endoscopic remission at Week 8 (Induction Study)

Subject analysis set title	MMS baseline ISB
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Modified Mayo Score by Induction Phase Treatment Group, Induction Study Baseline

Subject analysis set title	MMS baseline BOLS
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Modified Mayo Score by Induction Phase Treatment Group, Baseline of Open-Label Study

Subject analysis set title	MMS Week 48
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Modified Mayo Score by Induction Phase Treatment Group, Week 48

Subject analysis set title	MMS Week 96
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Modified Mayo Score by Induction Phase Treatment Group, Week 96

Subject analysis set title	pMMS baseline ISB
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Induction Study Baseline

Subject analysis set title	pMMS baseline BOLS
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Baseline of Open Label Study.

Subject analysis set title	pMMS Week 4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group: Week 4

Subject analysis set title	pMMS Week 8
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 8

Subject analysis set title	pMMS Week 12
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group: Week 12

Subject analysis set title	pMMS Week 16
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 16

Subject analysis set title	pMMS Week 20
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 20

Subject analysis set title	pMMS Week 24
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 24

Subject analysis set title	pMMS Week 28
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 28

Subject analysis set title	pMMS Week 32
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 32

Subject analysis set title	pMMS Week 36
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 36

Subject analysis set title	pMMS Week 40
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 40

Subject analysis set title	pMMS Week 44
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 44

Subject analysis set title	pMMS Week 48
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 48

Subject analysis set title	pMMS Week 60
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 60

Subject analysis set title	pMMS Week 72
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 72

Subject analysis set title	pMMS Week 84
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 84

Subject analysis set title	pMMS Week 96
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 96

Subject analysis set title	Stool frequency - Baseline ISB
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Baseline Induction Study Baseline

Subject analysis set title	Stool frequency - Baseline BOLS
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Baseline of Open Label Study

Subject analysis set title	Stool Frequency - Week 4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 4

Subject analysis set title	Stool Frequency - Week 8
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 8

Subject analysis set title	Stool Frequency - Week 12
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 12

Subject analysis set title	Stool Frequency - Week 16
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 16

Subject analysis set title	Stool Frequency - Week 20
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 20

Subject analysis set title	Stool Frequency - Week 24
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 24

Subject analysis set title	Stool Frequency - Week 28
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 28

Subject analysis set title	Stool Frequency - Week 32
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 32

Subject analysis set title	Stool Frequency - Week 36
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 36

Subject analysis set title	Stool Frequency - Week 40
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 40

Subject analysis set title	Stool Frequency - Week 44
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 44

Subject analysis set title	Stool Frequency - Week 48
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 48

Subject analysis set title	Stool Frequency - Week 60
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 60

Subject analysis set title	Stool Frequency - Week 72
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 72

Subject analysis set title	Stool Frequency - Week 84
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 84

Subject analysis set title	Stool Frequency - Week 96
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 96

Subject analysis set title	Rectal Bleeding Score - Baseline ISB
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore- Baseline Induction Study Baseline

Subject analysis set title	Rectal bleeding Score - BOLS
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Baseline of Open Label Study

Subject analysis set title	Rectal bleeding Score - Week 4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 4

Subject analysis set title	Rectal bleeding Score - Week 8
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 8

Subject analysis set title	Rectal bleeding Score - Week 12
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - week 12

Subject analysis set title	Rectal bleeding Score - Week 16
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 16

Subject analysis set title	Rectal bleeding Score - Week 20
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 20

Subject analysis set title	Rectal bleeding Score - Week 24
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 24

Subject analysis set title	Rectal bleeding Score - Week 28
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 28

Subject analysis set title	Rectal bleeding Score - Week 32
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 32

Subject analysis set title	Rectal bleeding Score - Week 36
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 36

Subject analysis set title	Rectal bleeding Score - Week 40
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 40

Subject analysis set title	Rectal bleeding Score - Week 44
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 44

Subject analysis set title	Rectal bleeding Score - Week 48
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 48

Subject analysis set title	Rectal bleeding Score - Week 60
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore- Week 60

Subject analysis set title	Rectal bleeding Score - Week 72
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 72

Subject analysis set title	Rectal bleeding Score - Week 84
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 84

Subject analysis set title	Rectal bleeding Score - Week 96
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 96

Subject analysis set title	C- Reactive Protein - Baseline BOLS
Subject analysis set type	Sub-group analysis

Subject analysis set description:

CRP by Induction Phase Treatment Group , Baseline - Baseline of Open Label Study

Subject analysis set title	C-Reactive Protein - Week 24
Subject analysis set type	Sub-group analysis

Subject analysis set description:

CRP by Induction Phase Treatment Group - Week 24

Subject analysis set title	C-Reactive Protein - Week 48
Subject analysis set type	Sub-group analysis

Subject analysis set description:

CRP by Induction Phase Treatment Group - Week 48

Reporting group values	Full analysis set [FAS]	Sustained endoscopic improvement at Week 8 of induction study	Sustained endoscopic remission at Week 8 of induction study
Number of subjects	217	70	16
Age categorical Units: Subjects			
Adults (18-64 years)	202		
From 65-84 years	15		
Age continuous Units: years			
arithmetic mean	42.1		
standard deviation	± 13.77	±	±
Gender categorical Units: Subjects			
Female	84		
Male	133		

Reporting group values	MMS baseline ISB	MMS baseline BOLS	MMS Week 48
Number of subjects	217	151	182
Age categorical Units: Subjects			
Adults (18-64 years)			
From 65-84 years			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			

Reporting group values	MMS Week 96	pMMS baseline ISB	pMMS baseline BOLS
Number of subjects	154	217	214
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			

Reporting group values	pMMS Week 4	pMMS Week 8	pMMS Week 12
Number of subjects	214	208	203
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			

Reporting group values	pMMS Week 16	pMMS Week 20	pMMS Week 24
Number of subjects	200	196	192
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±

Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	pMMS Week 28	pMMS Week 32	pMMS Week 36
Number of subjects	191	189	188
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	pMMS Week 40	pMMS Week 44	pMMS Week 48
Number of subjects	185	182	184
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	pMMS Week 60	pMMS Week 72	pMMS Week 84
Number of subjects	175	170	169
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	pMMS Week 96	Stool frequency - Baseline ISB	Stool frequency - Baseline BOLS
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Number of subjects	165	217	214
Age categorical			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			

Reporting group values	Stool Frequency - Week 4	Stool Frequency - Week 8	Stool Frequency - Week 12
Number of subjects	214	209	203
Age categorical			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			

Reporting group values	Stool Frequency - Week 16	Stool Frequency - Week 20	Stool Frequency - Week 24
Number of subjects	202	198	193
Age categorical			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	±
Gender categorical			
Units: Subjects			
Female			
Male			

Reporting group values	Stool Frequency - Week 28	Stool Frequency - Week 32	Stool Frequency - Week 36
Number of subjects	192	190	189
Age categorical			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			

Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	Stool Frequency - Week 40	Stool Frequency - Week 44	Stool Frequency - Week 48
Number of subjects	185	182	184
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	Stool Frequency - Week 60	Stool Frequency - Week 72	Stool Frequency - Week 84
Number of subjects	176	170	169
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	Stool Frequency - Week 96	Rectal Bleeding Score - Baseline ISB	Rectal bleeding Score - BOLS
Number of subjects	165	217	214
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±

Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	Rectal bleeding Score - Week 4	Rectal bleeding Score - Week 8	Rectal bleeding Score - Week 12
Number of subjects	208	208	203
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	Rectal bleeding Score - Week 16	Rectal bleeding Score - Week 20	Rectal bleeding Score - Week 24
Number of subjects	200	196	192
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	Rectal bleeding Score - Week 28	Rectal bleeding Score - Week 32	Rectal bleeding Score - Week 36
Number of subjects	191	189	188
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	Rectal bleeding Score - Week 40	Rectal bleeding Score - Week 44	Rectal bleeding Score - Week 48
Number of subjects	185	182	184
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			

Reporting group values	Rectal bleeding Score - Week 60	Rectal bleeding Score - Week 72	Rectal bleeding Score - Week 84
Number of subjects	175	170	169
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			

Reporting group values	Rectal bleeding Score - Week 96	C- Reactive Protein - Baseline BOLS	C-Reactive Protein - Week 24
Number of subjects	165	216	191
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	±	±	±
Gender categorical Units: Subjects			
Female Male			

Reporting group values	C-Reactive Protein - Week 48		
Number of subjects	183		

Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years			
Age continuous Units: years arithmetic mean standard deviation	$\pm$		
Gender categorical Units: Subjects			
Female Male			

End points

End points reporting groups

Reporting group title	ABX464 50 mg
Reporting group description: All subjects will receive ABX464 administered at 50 mg o.d for an overall period of 96 weeks.	
Subject analysis set title	Full analysis set [FAS]
Subject analysis set type	Full analysis
Subject analysis set description: The FAS included all patients in the study who received at least one dose of the study treatment, and who had BOLS (Baseline of the open-label study) data for at least one efficacy variable.	
Subject analysis set title	Sustained endoscopic improvement at Week 8 of induction study
Subject analysis set type	Sub-group analysis
Subject analysis set description: At Week 8 of the induction study, endoscopic improvement was achieved by 70 patients	
Subject analysis set title	Sustained endoscopic remission at Week 8 of induction study
Subject analysis set type	Sub-group analysis
Subject analysis set description: number of patients who achieved endoscopic remission at Week 8 (Induction Study)	
Subject analysis set title	MMS baseline ISB
Subject analysis set type	Sub-group analysis
Subject analysis set description: Modified Mayo Score by Induction Phase Treatment Group, Induction Study Baseline	
Subject analysis set title	MMS baseline BOLS
Subject analysis set type	Sub-group analysis
Subject analysis set description: Modified Mayo Score by Induction Phase Treatment Group, Baseline of Open-Label Study	
Subject analysis set title	MMS Week 48
Subject analysis set type	Sub-group analysis
Subject analysis set description: Modified Mayo Score by Induction Phase Treatment Group, Week 48	
Subject analysis set title	MMS Week 96
Subject analysis set type	Sub-group analysis
Subject analysis set description: Modified Mayo Score by Induction Phase Treatment Group, Week 96	
Subject analysis set title	pMMS baseline ISB
Subject analysis set type	Sub-group analysis
Subject analysis set description: Partial Modified Mayo Score by Induction Phase Treatment Group, Induction Study Baseline	
Subject analysis set title	pMMS baseline BOLS
Subject analysis set type	Sub-group analysis
Subject analysis set description: Partial Modified Mayo Score by Induction Phase Treatment Group, Baseline of Open Label Study.	
Subject analysis set title	pMMS Week 4
Subject analysis set type	Sub-group analysis
Subject analysis set description: Partial Modified Mayo Score by Induction Phase Treatment Group: Week 4	
Subject analysis set title	pMMS Week 8
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 8

Subject analysis set title	pMMS Week 12
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group: Week 12

Subject analysis set title	pMMS Week 16
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 16

Subject analysis set title	pMMS Week 20
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 20

Subject analysis set title	pMMS Week 24
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 24

Subject analysis set title	pMMS Week 28
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 28

Subject analysis set title	pMMS Week 32
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 32

Subject analysis set title	pMMS Week 36
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 36

Subject analysis set title	pMMS Week 40
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 40

Subject analysis set title	pMMS Week 44
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 44

Subject analysis set title	pMMS Week 48
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 48

Subject analysis set title	pMMS Week 60
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 60

Subject analysis set title	pMMS Week 72
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 72

Subject analysis set title	pMMS Week 84
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 84

Subject analysis set title	pMMS Week 96
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Partial Modified Mayo Score by Induction Phase Treatment Group, Week 96

Subject analysis set title	Stool frequency - Baseline ISB
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Baseline Induction Study Baseline

Subject analysis set title	Stool frequency - Baseline BOLS
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Baseline of Open Label Study

Subject analysis set title	Stool Frequency - Week 4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 4

Subject analysis set title	Stool Frequency - Week 8
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 8

Subject analysis set title	Stool Frequency - Week 12
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 12

Subject analysis set title	Stool Frequency - Week 16
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 16

Subject analysis set title	Stool Frequency - Week 20
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 20

Subject analysis set title	Stool Frequency - Week 24
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 24

Subject analysis set title	Stool Frequency - Week 28
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 28

Subject analysis set title	Stool Frequency - Week 32
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 32

Subject analysis set title	Stool Frequency - Week 36
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 36

Subject analysis set title	Stool Frequency - Week 40
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 40

Subject analysis set title	Stool Frequency - Week 44
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 44

Subject analysis set title	Stool Frequency - Week 48
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 48

Subject analysis set title	Stool Frequency - Week 60
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 60

Subject analysis set title	Stool Frequency - Week 72
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 72

Subject analysis set title	Stool Frequency - Week 84
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 84

Subject analysis set title	Stool Frequency - Week 96
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Stool Frequency Subscore, Week 96

Subject analysis set title	Rectal Bleeding Score - Baseline ISB
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore- Baseline Induction Study Baseline

Subject analysis set title	Rectal bleeding Score - BOLS
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Baseline of Open Label Study

Subject analysis set title	Rectal bleeding Score - Week 4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 4

Subject analysis set title	Rectal bleeding Score - Week 8
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 8

Subject analysis set title	Rectal bleeding Score - Week 12
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - week 12

Subject analysis set title	Rectal bleeding Score - Week 16
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 16

Subject analysis set title	Rectal bleeding Score - Week 20
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 20

Subject analysis set title	Rectal bleeding Score - Week 24
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 24

Subject analysis set title	Rectal bleeding Score - Week 28
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 28

Subject analysis set title	Rectal bleeding Score - Week 32
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 32

Subject analysis set title	Rectal bleeding Score - Week 36
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 36

Subject analysis set title	Rectal bleeding Score - Week 40
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 40

Subject analysis set title	Rectal bleeding Score - Week 44
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 44

Subject analysis set title	Rectal bleeding Score - Week 48
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 48

Subject analysis set title	Rectal bleeding Score - Week 60
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore- Week 60

Subject analysis set title	Rectal bleeding Score - Week 72
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 72

Subject analysis set title	Rectal bleeding Score - Week 84
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 84

Subject analysis set title	Rectal bleeding Score - Week 96
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Rectal Bleeding Subscore - Week 96

Subject analysis set title	C- Reactive Protein - Baseline BOLS
Subject analysis set type	Sub-group analysis

Subject analysis set description:

CRP by Induction Phase Treatment Group , Baseline - Baseline of Open Label Study

Subject analysis set title	C-Reactive Protein - Week 24
Subject analysis set type	Sub-group analysis

Subject analysis set description:

CRP by Induction Phase Treatment Group - Week 24

Subject analysis set title	C-Reactive Protein - Week 48
Subject analysis set type	Sub-group analysis

Subject analysis set description:

CRP by Induction Phase Treatment Group - Week 48

Primary: Proportion of Patients With Clinical Remission at Week 48 Compared to Baseline of Induction Study (ABX464-103)

End point title	Proportion of Patients With Clinical Remission at Week 48 Compared to Baseline of Induction Study (ABX464-103) ^[1]
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End point description:

Clinical remission (based on the Mayo scoring system) is defined as: a rectal bleeding sub-score = 0, and an endoscopy sub-score ≤1 (excluding friability), and at least 1-point decrease in stool frequency sub-score from baseline to achieve a stool frequency sub-score ≤1

End point type	Primary
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End point timeframe:

week 48

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: Descriptive Statistics were done.

End point values	ABX464 50 mg	Full analysis set [FAS]		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	217	217		
Units: participants	119	119		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Clinical Response at Weeks 48 and 96 Compared to Baseline of Induction Study

End point title	Proportion of Patients With Clinical Response at Weeks 48 and 96 Compared to Baseline of Induction Study
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End point description:

Proportion of patients with clinical response at week 48 Clinical response is defined as: a reduction in Mayo Score ≥ 3 points and ≥ 30 % from baseline with an accompanying decrease in rectal bleeding sub-score ≥ 1 point or absolute rectal bleeding sub-score ≤ 1 point.

End point type	Secondary
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End point timeframe:

Weeks 48 and 96

End point values	ABX464 50 mg	Full analysis set [FAS]		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	217	217		
Units: participants				
Week 48	177	177		
Week 96	158	158		

Statistical analyses

No statistical analyses for this end point

Secondary: Endoscopic Improvement at Weeks 48 and 96

End point title	Endoscopic Improvement at Weeks 48 and 96
End point description:	
Proportion of patients with endoscopic improvement at week 48 among all patients.	
Proportion of patients with endoscopic improvement at week 96 among all patients.	
Endoscopic improvement is defined as a Mayo endoscopic sub score of ≤ 1 (excluding friability).	
End point type	Secondary
End point timeframe:	
week 48 and week 96	

End point values	ABX464 50 mg	Full analysis set [FAS]		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	217	217		
Units: participants				
Week 48	133	133		
Week 96	128	128		

Statistical analyses

No statistical analyses for this end point

Secondary: Endoscopic Remission at Weeks 48 and 96

End point title	Endoscopic Remission at Weeks 48 and 96
End point description:	
Proportion of patients with endoscopic remission at week 48 among all patients. Proportion of patients with endoscopic remission at week 96 among all patients. Endoscopic remission is defined as a Mayo endoscopic sub score of 0.	
End point type	Secondary
End point timeframe:	
week 48 and week 96	

End point values	ABX464 50 mg	Full analysis set [FAS]		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	217	217		
Units: participants				
Week 48	72	72		
Week 96	78	78		

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
Participants recorded stool frequency using a paper subject diary on a daily basis. The stool frequency subscore ranges from 0 to 3 according to the following scale: Score 0: Normal number of stools Score 1: 1 to 2 stools per day more than normal Score 2: 3 to 4 stools per day more than normal Score 3: 5 or more stools per day more than normal	
End point type	Secondary
End point timeframe:	
Baseline ISB	

End point values	Stool frequency - Baseline ISB			
Subject group type	Subject analysis set			
Number of subjects analysed	217			
Units: score on a scale				
arithmetic mean (standard deviation)				
Stool frequency - Baseline ISB	2.6 (± 0.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: miRNA-124 Expression

End point title	miRNA-124 Expression
End point description:	
Change relative to baseline in miRNA-124 expression in rectal/sigmoidal biopsies at week 48 and in total blood at week 24 and week 48.	
End point type	Secondary

End point timeframe:
baseline, week 24 and week 48

End point values	ABX464 50 mg	Full analysis set [FAS]		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	217	217		
Units: copy number/cell				
arithmetic mean (standard deviation)				
miR-124 - Rectal - Baseline	0.0065 (± 0.00211)	0.00065 (± 0.00211)		
miR-124 - Rectal - Week 48	0.00255 (± 0.00252)	0.00255 (± 0.00252)		
miR-124 - Sigmoidal- Baseline	0.00035 (± 0.00050)	0.00035 (± 0.00050)		
miR-124 - Sigmoidal- Week 48	0.00225 (± 0.00216)	0.00225 (± 0.00216)		
miR-124 - Blood- Baseline	0.00000 (± 0.00000)	0.00000 (± 0.00000)		
miR-124 - Blood- Week 24	0.00011 (± 0.00015)	0.00011 (± 0.00015)		
miR-124 - Blood- Week 48	0.00013 (± 0.00026)	0.00013 (± 0.00026)		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence and Description of Adverse Events

End point title	Incidence and Description of Adverse Events
End point description: Number and rate of all adverse events, causally-related adverse events, all serious adverse events and causally-related serious adverse events classified by severity. Incidence of treatment-emergent serious adverse events, hospitalizations, total inpatient days. Incidence of adverse events leading to investigational product discontinuation. Number of clinically significant laboratory abnormalities.	
End point type	Secondary
End point timeframe: From baseline to week 96	

End point values	ABX464 50 mg	Full analysis set [FAS]		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	217	217		
Units: participants				
AEs	149	149		
TEAEs	148	148		
Related TEAEs	54	54		

SAEs	18	18		
TESAEs	18	18		
TEAEs leading to discontinuation of IP	26	26		
TEAEs leading to study discontinuation	17	17		

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
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End point description:

End point type	Secondary
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End point timeframe:

Baseline BOLS

End point values	Stool frequency - Baseline BOLS			
Subject group type	Subject analysis set			
Number of subjects analysed	214			
Units: score on a scale				
arithmetic mean (standard deviation)	1.4 ($\pm$ 0.94)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
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End point description:

End point type	Secondary
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End point timeframe:

Week 4

End point values	Stool Frequency - Week 4			
Subject group type	Subject analysis set			
Number of subjects analysed	214			
Units: score on scale				
arithmetic mean (standard deviation)	1.2 ($\pm$ 0.89)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 8	

End point values	Stool Frequency - Week 8			
Subject group type	Subject analysis set			
Number of subjects analysed	213			
Units: score on a scale				
arithmetic mean (standard deviation)	1.2 ($\pm$ 0.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 12	

End point values	Stool Frequency - Week 12			
Subject group type	Subject analysis set			
Number of subjects analysed	203			
Units: score on a scale				
arithmetic mean (standard deviation)	1.1 ($\pm$ 0.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 16	

End point values	Stool Frequency - Week 16			
Subject group type	Subject analysis set			
Number of subjects analysed	202			
Units: score on a scale				
arithmetic mean (standard deviation)	1.1 ($\pm$ 0.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 20	

End point values	Stool Frequency - Week 20			
Subject group type	Subject analysis set			
Number of subjects analysed	198			
Units: score on a scale				
arithmetic mean (standard deviation)	1.0 ($\pm$ 0.92)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 24	

End point values	Stool Frequency - Week 24			
Subject group type	Subject analysis set			
Number of subjects analysed	193			
Units: score on a scale				
arithmetic mean (standard deviation)	1.0 ($\pm$ 0.83)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
Stool Frequency - Week 28	
End point type	Secondary
End point timeframe:	
Week 28	

End point values	Stool Frequency - Week 28			
Subject group type	Subject analysis set			
Number of subjects analysed	192			
Units: score on a scale				
arithmetic mean (standard deviation)	0.9 ($\pm$ 0.87)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 32	

End point values	Stool Frequency - Week 32			
Subject group type	Subject analysis set			
Number of subjects analysed	190			
Units: score on a scale				
arithmetic mean (standard deviation)	0.9 ($\pm$ 0.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 40	

End point values	Stool Frequency - Week 40			
Subject group type	Subject analysis set			
Number of subjects analysed	185			
Units: score on a scale				
arithmetic mean (standard deviation)	0.8 (± 0.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 36	

End point values	Stool Frequency - Week 36			
Subject group type	Subject analysis set			
Number of subjects analysed	182			
Units: score on a scale				
arithmetic mean (standard deviation)	0.9 (± 0.82)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 44	

End point values	Stool Frequency - Week 44			
Subject group type	Subject analysis set			
Number of subjects analysed	182			
Units: score on a scale				
arithmetic mean (standard deviation)	0.8 (± 0.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 48	

End point values	Stool Frequency - Week 48			
Subject group type	Subject analysis set			
Number of subjects analysed	184			
Units: score on scale				
arithmetic mean (standard deviation)	0.7 (± 0.79)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 60	

End point values	Stool Frequency - Week 60			
Subject group type	Subject analysis set			
Number of subjects analysed	176			
Units: score on a scale				
arithmetic mean (standard deviation)	0.7 ($\pm$ 0.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 72	

End point values	Stool Frequency - Week 72			
Subject group type	Subject analysis set			
Number of subjects analysed	170			
Units: score on a scale				
arithmetic mean (standard deviation)	0.7 ($\pm$ 0.76)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 84	

End point values	Stool Frequency - Week 84			
Subject group type	Subject analysis set			
Number of subjects analysed	169			
Units: score on a scale				
arithmetic mean (standard deviation)	0.7 ($\pm$ 0.77)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stool Frequency Subscore

End point title	Stool Frequency Subscore
End point description:	
End point type	Secondary
End point timeframe:	
Week 96	

End point values	Stool Frequency - Week 96			
Subject group type	Subject analysis set			
Number of subjects analysed	165			
Units: score on a scale				
arithmetic mean (standard deviation)	0.6 ($\pm$ 0.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein levels

End point title	C-Reactive Protein levels
End point description:	
Change to baseline in C-Reactive Protein levels. Number analyzed correspond to number of patients analysed in the relevant week	
End point type	Secondary
End point timeframe:	
Baseline BOLS	

End point values	ABX464 50 mg			
Subject group type	Reporting group			
Number of subjects analysed	216			
Units: mg/L				
arithmetic mean (standard deviation)	6.66 (± 12.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein levels

End point title	C-Reactive Protein levels
End point description: Change to baseline in C-Reactive Protein levels. Number analyzed correspond to number of patients analysed in the relevant week.	
End point type	Secondary
End point timeframe: Week 24	

End point values	C-Reactive Protein - Week 24			
Subject group type	Subject analysis set			
Number of subjects analysed	191			
Units: mg/L				
arithmetic mean (standard deviation)	5.07 (± 10.43)			

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein levels

End point title	C-Reactive Protein levels
End point description: Change to baseline in C-Reactive Protein levels. Number analyzed correspond to number of patients analysed in the relevant week	
End point type	Secondary
End point timeframe: Week 48	

End point values	C-Reactive Protein - Week 48			
Subject group type	Subject analysis set			
Number of subjects analysed	183			
Units: mg/L				
arithmetic mean (standard deviation)	5.01 (± 11.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
Participants recorded rectal bleeding in a paper subject diary on a daily basis. Rectal bleeding score is taken as the worst subscore of the three most recent scores within 7 days prior to the visit. The rectal bleeding subscore ranges from 0 to 3 according to the following scale:	
Score 0: No blood seen	
Score 1: Streaks of blood with stool less than half the time	
Score 2: Obvious blood with stool most of the time	
Score 3: Blood alone passed A lower score represents an improvement in rectal bleeding.	
End point type	Secondary
End point timeframe:	
Baseline - ISB	

End point values	Rectal Bleeding Score - Baseline ISB			
Subject group type	Subject analysis set			
Number of subjects analysed	217			
Units: score on a scale				
arithmetic mean (standard deviation)	1.6 (± 0.72)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Baseline - BOLS	

End point values	Rectal bleeding Score - BOLS			
Subject group type	Subject analysis set			
Number of subjects analysed	214			
Units: score on a scale				
arithmetic mean (standard deviation)	0.4 (± 0.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 4	

End point values	Rectal bleeding Score - Week 4			
Subject group type	Subject analysis set			
Number of subjects analysed	214			
Units: score on scale				
arithmetic mean (standard deviation)	0.2 (± 0.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 8	

End point values	Stool Frequency - Week 8			
Subject group type	Subject analysis set			
Number of subjects analysed	208			
Units: score on a scale				
arithmetic mean (standard deviation)	0.2 ($\pm$ 0.56)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 12	

End point values	Rectal bleeding Score - Week 12			
Subject group type	Subject analysis set			
Number of subjects analysed	203			
Units: score on a scale				
arithmetic mean (standard deviation)	0.2 ($\pm$ 0.50)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 16	

End point values	Rectal bleeding Score - Week 16			
Subject group type	Subject analysis set			
Number of subjects analysed	200			
Units: score on a scale				
arithmetic mean (standard deviation)	0.2 ($\pm$ 0.51)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 20	

End point values	Rectal bleeding Score - Week 20			
Subject group type	Subject analysis set			
Number of subjects analysed	196			
Units: score on a scale				
arithmetic mean (standard deviation)	0.2 ($\pm$ 0.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 24	

End point values	Rectal bleeding Score - Week 24			
Subject group type	Subject analysis set			
Number of subjects analysed	192			
Units: score on a scale				
arithmetic mean (standard deviation)	0.2 ($\pm$ 0.46)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 28	

End point values	Rectal bleeding Score - Week 28			
Subject group type	Subject analysis set			
Number of subjects analysed	191			
Units: score on a scale				
arithmetic mean (standard deviation)	0.1 ($\pm$ 0.42)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 32	

End point values	Rectal bleeding Score - Week 32			
Subject group type	Subject analysis set			
Number of subjects analysed	189			
Units: score on a scale				
arithmetic mean (standard deviation)	0.1 (± 0.39)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 36	

End point values	Rectal bleeding Score - Week 36			
Subject group type	Subject analysis set			
Number of subjects analysed	188			
Units: score on a scale				
arithmetic mean (standard deviation)	0.1 (± 0.38)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 40	

End point values	Rectal bleeding Score - Week 40			
Subject group type	Subject analysis set			
Number of subjects analysed	185			
Units: score on a scale				
arithmetic mean (standard deviation)	0.1 ($\pm$ 0.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 44	

End point values	Rectal bleeding Score - Week 44			
Subject group type	Subject analysis set			
Number of subjects analysed	182			
Units: score on a scale				
arithmetic mean (standard deviation)	0.1 ($\pm$ 0.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 48	

End point values	Rectal bleeding Score - Week 48			
Subject group type	Subject analysis set			
Number of subjects analysed	184			
Units: score on a scale				
arithmetic mean (standard deviation)	0.0 ($\pm$ 0.23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 60	

End point values	Rectal bleeding Score - Week 60			
Subject group type	Subject analysis set			
Number of subjects analysed	175			
Units: score on a scale				
arithmetic mean (standard deviation)	0.0 ($\pm$ 0.24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 72	

End point values	Rectal bleeding Score - Week 72			
Subject group type	Subject analysis set			
Number of subjects analysed	170			
Units: score on a scale				
arithmetic mean (standard deviation)	0.0 ($\pm$ 0.24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 84	

End point values	Rectal bleeding Score - Week 84			
Subject group type	Subject analysis set			
Number of subjects analysed	169			
Units: score on a scale				
arithmetic mean (standard deviation)	0.1 ($\pm$ 0.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rectal Bleeding Score

End point title	Rectal Bleeding Score
End point description:	
End point type	Secondary
End point timeframe:	
Week 96	

End point values	Rectal bleeding Score - Week 96			
Subject group type	Subject analysis set			
Number of subjects analysed	165			
Units: score on a scale				
arithmetic mean (standard deviation)	0.0 ($\pm$ 0.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
Change in Modified Mayo Score (MMS) at weeks 48 and 96 and in partial Modified Mayo Score (pMMS) MMS is a composite score of UC disease activity calculated as the sum of the following 3 subscores: 1. Stool frequency, scored from 0 (normal number of stools) to 3 (5 or more stools more than normal). 2. Rectal bleeding, scored from 0 (no blood seen) to 3 (blood alone passed). 3. Endoscopic evaluation, scored from 0 (normal or inactive disease) to 3 (severe disease, spontaneous bleeding, ulceration). The overall MMS ranges from 0 to 9 where higher scores represent more severe disease. pMMS is a composite score of UC disease activity calculated as the sum of the following 2 subscores: 1. Stool frequency, scored from 0 (normal number of stools) to 3 (5 or more stools more than normal). 2. Rectal bleeding, scored from 0 (no blood seen) to 3 (blood alone passed). The overall pMMS ranges from 0 to 6 where higher scores represent more severe disease.	
End point type	Secondary
End point timeframe:	
MMS Baseline ISB	

End point values	MMS baseline ISB			
Subject group type	Subject analysis set			
Number of subjects analysed	217			
Units: units on a scale				
arithmetic mean (standard deviation)	7.0 ($\pm$ 1.07)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	
Secondary	

End point timeframe:

MMS baseline BOLS

End point values	MMS baseline BOLS			
Subject group type	Subject analysis set			
Number of subjects analysed	151			
Units: units on a scale				
arithmetic mean (standard deviation)	4.0 ($\pm$ 2.02)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
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End point description:

End point type	Secondary
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End point timeframe:

MMS Week 48

End point values	MMS Week 48			
Subject group type	Subject analysis set			
Number of subjects analysed	182			
Units: units on a scale				
arithmetic mean (standard deviation)	1.8 ($\pm$ 1.47)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
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End point description:

End point type	Secondary
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End point timeframe:

MMS Week 96

End point values	MMS Week 96			
Subject group type	Subject analysis set			
Number of subjects analysed	154			
Units: units on a scale				
arithmetic mean (standard deviation)	1.5 ($\pm$ 1.48)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS baseline ISB	

End point values	pMMS baseline ISB			
Subject group type	Subject analysis set			
Number of subjects analysed	217			
Units: units on a scale				
arithmetic mean (standard deviation)	4.2 ($\pm$ 1.01)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS baseline BOLS	

End point values	pMMS baseline BOLS			
Subject group type	Subject analysis set			
Number of subjects analysed	214			
Units: units on a scale				
arithmetic mean (standard deviation)	1.8 ($\pm$ 1.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 4	

End point values	pMMS Week 4			
Subject group type	Subject analysis set			
Number of subjects analysed	214			
Units: units on a scale				
arithmetic mean (standard deviation)	1.4 ($\pm$ 1.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 8	

End point values	pMMS Week 8			
Subject group type	Subject analysis set			
Number of subjects analysed	208			
Units: units on a scale				
arithmetic mean (standard deviation)	1.4 ($\pm$ 1.24)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 12	

End point values	pMMS Week 12			
Subject group type	Subject analysis set			
Number of subjects analysed	203			
Units: units on a scale				
arithmetic mean (standard deviation)	1.3 ($\pm$ 1.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 16	

End point values	pMMS Week 16			
Subject group type	Subject analysis set			
Number of subjects analysed	200			
Units: units on a scale				
arithmetic mean (standard deviation)	1.3 ($\pm$ 1.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 20	

End point values	pMMS Week 20			
Subject group type	Subject analysis set			
Number of subjects analysed	196			
Units: units on a scale				
arithmetic mean (standard deviation)	1.2 ($\pm$ 1.14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 24	

End point values	pMMS Week 24			
Subject group type	Subject analysis set			
Number of subjects analysed	192			
Units: units on a scale				
arithmetic mean (standard deviation)	1.1 ($\pm$ 1.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 28	

End point values	pMMS Week 28			
Subject group type	Subject analysis set			
Number of subjects analysed	191			
Units: units on a scale				
arithmetic mean (standard deviation)	1.1 ($\pm$ 1.09)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 32	

End point values	pMMS Week 32			
Subject group type	Subject analysis set			
Number of subjects analysed	189			
Units: units on a scale				
arithmetic mean (standard deviation)	1.0 ($\pm$ 1.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 36	

End point values	pMMS Week 36			
Subject group type	Subject analysis set			
Number of subjects analysed	188			
Units: units on a scale				
arithmetic mean (standard deviation)	1.0 ($\pm$ 0.98)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 40	

End point values	pMMS Week 40			
Subject group type	Subject analysis set			
Number of subjects analysed	185			
Units: units on a scale				
arithmetic mean (standard deviation)	0.9 ($\pm$ 0.94)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 44	

End point values	pMMS Week 44			
Subject group type	Subject analysis set			
Number of subjects analysed	182			
Units: units on a scale				
arithmetic mean (standard deviation)	0.9 ($\pm$ 0.98)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
Stool Frequency - Week 48	

End point values	Stool Frequency - Week 48			
Subject group type	Subject analysis set			
Number of subjects analysed	184			
Units: units on a scale				
arithmetic mean (standard deviation)	0.8 ($\pm$ 0.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 60	

End point values	pMMS Week 60			
Subject group type	Subject analysis set			
Number of subjects analysed	175			
Units: units on a scale				
arithmetic mean (standard deviation)	0.7 ($\pm$ 0.80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 72	

End point values	pMMS Week 72			
Subject group type	Subject analysis set			
Number of subjects analysed	170			
Units: units on a scale				
arithmetic mean (standard deviation)	0.7 ($\pm$ 0.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 84	

End point values	pMMS Week 84			
Subject group type	Subject analysis set			
Number of subjects analysed	169			
Units: units on a scale				
arithmetic mean (standard deviation)	0.7 ($\pm$ 0.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Modified Mayo Score and in Partial Modified Mayo Score

End point title	Change in Modified Mayo Score and in Partial Modified Mayo Score
End point description:	
End point type	Secondary
End point timeframe:	
pMMS Week 96	

End point values	pMMS Week 96			
Subject group type	Subject analysis set			
Number of subjects analysed	165			
Units: units on a scale				
arithmetic mean (standard deviation)	0.7 ($\pm$ 0.79)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sustained Endoscopic Changes at Week 48 and Week 96

End point title	Sustained Endoscopic Changes at Week 48 and Week 96
End point description:	Proportion of patients with sustained endoscopic changes at week 48 and 96. Sustained endoscopic changes is defined as the number of patients with endoscopic changes at week 48 among patients who had endoscopic changes during the Induction study (at week 8 or week 16 of study ABX464-103).
End point type	Secondary
End point timeframe:	weeks 48

End point values	Sustained endoscopic improvement at Week 8 of induction study			
Subject group type	Subject analysis set			
Number of subjects analysed	70			
Units: participants				
Sustained endoscopic improvement at Week 8 of indu	53			

Statistical analyses

No statistical analyses for this end point

Secondary: Sustained Endoscopic Changes at Week 48 and Week 96

End point title	Sustained Endoscopic Changes at Week 48 and Week 96
End point description:	
End point type	Secondary
End point timeframe:	week 96

End point values	Sustained endoscopic improvement at Week 8 of induction study			
Subject group type	Subject analysis set			
Number of subjects analysed	70			
Units: participants	50			

Statistical analyses

No statistical analyses for this end point

Secondary: Sustained Endoscopic Changes at Week 48 and Week 96

End point title	Sustained Endoscopic Changes at Week 48 and Week 96
End point description:	
End point type	Secondary
End point timeframe: week 48	

End point values	Sustained endoscopic remission at Week 8 of induction study			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: participants	13			

Statistical analyses

No statistical analyses for this end point

Secondary: Sustained Endoscopic Changes at Week 48 and Week 96

End point title	Sustained Endoscopic Changes at Week 48 and Week 96
End point description:	
End point type	Secondary
End point timeframe: week 96	

End point values	Sustained endoscopic remission at Week 8 of induction study			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: participants	11			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

96 weeks

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	ABX464 50 mg
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Reporting group description: -

Serious adverse events	ABX464 50 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 217 (8.29%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Meningioma malignant			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Injury			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Left ventricular dysfunction			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Palpitations			

subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Facial paresis			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Ischemic stroke			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Polyneuropathy			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colon dysplasia			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Proctitis			
subjects affected / exposed	2 / 217 (0.92%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast			

disorders			
Cervical dysplasia			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Apendicitis			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 217 (0.46%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	ABX464 50 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	148 / 217 (68.20%)		
Investigations			
Blood cholesterol increased			
subjects affected / exposed	8 / 217 (3.69%)		
occurrences (all)	10		
C-reactive protein increased			
subjects affected / exposed	6 / 217 (2.76%)		
occurrences (all)	7		
Low density lipoprotein increased			
subjects affected / exposed	5 / 217 (2.30%)		
occurrences (all)	7		
Alanine aminotransferase increased			
subjects affected / exposed	4 / 217 (1.84%)		
occurrences (all)	6		
Neutrophil count increased			
subjects affected / exposed	4 / 217 (1.84%)		
occurrences (all)	4		
Thyroxine increased			
subjects affected / exposed	4 / 217 (1.84%)		
occurrences (all)	4		
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 217 (1.38%)		
occurrences (all)	3		
Lipase increased			
subjects affected / exposed	3 / 217 (1.38%)		
occurrences (all)	3		
Platelet count decreased			
subjects affected / exposed	3 / 217 (1.38%)		
occurrences (all)	3		
SARS-CoV-2 test positive			
subjects affected / exposed	3 / 217 (1.38%)		
occurrences (all)	3		
Fecal calprotectin increased			

subjects affected / exposed occurrences (all)	10 / 217 (4.61%) 11		
Injury, poisoning and procedural complications Vaccination complication subjects affected / exposed occurrences (all)	5 / 217 (2.30%) 12		
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	8 / 217 (3.69%) 8		
Cardiac disorders Palpitations subjects affected / exposed occurrences (all)	3 / 217 (1.38%) 4		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	25 / 217 (11.52%) 35		
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	4 / 217 (1.84%) 4 4 / 217 (1.84%) 4		
Blood and lymphatic system disorders Anemia subjects affected / exposed occurrences (all)	4 / 217 (1.84%) 5		
Gastrointestinal disorders Colitis ulcerative subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Nausea	17 / 217 (7.83%) 20 8 / 217 (3.69%) 10		

subjects affected / exposed occurrences (all)	8 / 217 (3.69%) 8		
Hemorrhoids subjects affected / exposed occurrences (all)	7 / 217 (3.23%) 7		
Diarrhea subjects affected / exposed occurrences (all)	4 / 217 (1.84%) 5		
Gastroesophageal reflux disease subjects affected / exposed occurrences (all)	5 / 217 (2.30%) 5		
Abdominal distension subjects affected / exposed occurrences (all)	3 / 217 (1.38%) 3		
Constipation subjects affected / exposed occurrences (all)	3 / 217 (1.38%) 3		
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	3 / 217 (1.38%) 3		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	11 / 217 (5.07%) 15		
Back pain subjects affected / exposed occurrences (all)	12 / 217 (5.53%) 13		
Pain in extremity subjects affected / exposed occurrences (all)	3 / 217 (1.38%) 6		
Myalgia subjects affected / exposed occurrences (all)	4 / 217 (1.84%) 5		
Osteoarthritis			

subjects affected / exposed	4 / 217 (1.84%)		
occurrences (all)	5		
Bursitis			
subjects affected / exposed	3 / 217 (1.38%)		
occurrences (all)	3		
Infections and infestations			
COVID-19			
subjects affected / exposed	31 / 217 (14.29%)		
occurrences (all)	34		
Nasopharyngitis			
subjects affected / exposed	15 / 217 (6.91%)		
occurrences (all)	23		
Upper respiratory tract infection			
subjects affected / exposed	6 / 217 (2.76%)		
occurrences (all)	7		
Pharyngitis			
subjects affected / exposed	4 / 217 (1.84%)		
occurrences (all)	4		
Sinusitis			
subjects affected / exposed	3 / 217 (1.38%)		
occurrences (all)	3		
Ear infection			
subjects affected / exposed	3 / 217 (1.38%)		
occurrences (all)	3		
Metabolism and nutrition disorders			
Hypophosphatemia			
subjects affected / exposed	5 / 217 (2.30%)		
occurrences (all)	7		
Folate deficiency			
subjects affected / exposed	6 / 217 (2.76%)		
occurrences (all)	6		
Hypercholesterolemia			
subjects affected / exposed	3 / 217 (1.38%)		
occurrences (all)	3		
Vitamin D deficiency			

subjects affected / exposed	3 / 217 (1.38%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 July 2019	The protocol was amended to add Geboes and Nancy Histology Scoring Scales, increase period of contraception use to 6 months, updated allowed doses of prednisone or equivalent and budesonide MMX to reflect standard doses used in participating countries, updated blood sample tubes and volumes, added annex 13 of the EudraLex guidelines for Good Manufacturing Practices.
10 September 2020	The protocol was amended to change from a 48-week to a 96-week study treatment schedule, change clinical response definition based on MMS, add sustained endoscopic remission endpoint, change clinical remission definition, add study endpoints regarding study treatment period extension, add inclusion criteria regarding second year of study treatment, add prohibited concomitant medications, include DSMB review study safety every 2 months, remove lifestyle guidelines, and add urine pregnancy tests monthly from Week 48 onward.
16 August 2021	The protocol was amendment to add miRNA dosage at Week 96, include eligibility check and signature of ICF at Week 48, add possibility to take part in long-term follow-up safety study (ABX464-108), add echocardiography measurements and add reason for discontinuation for patients with history of cardiac ischemic disease and/or congestive heart failure, implement designated independent cardiovascular safety adjudication committee, and to remove exclusion criteria 1: patients who had protocol deviation(s) in the induction study assessed as major by the investigator or Sponsor.
08 September 2021	The protocol was amended to include administration changes, and the addition of EU Regulation 536/2014 of the European Parliament and of Council, which introduces the Clinical Trials Information System (CTIS) that harmonizes the submission, assessment, and supervision process for clinical trials throughout Europe.
11 July 2022	The protocol was amended to align with the IB v8.0, clarify that only 2-dimensional echocardiography will be performed by sites, clarify local read results could be used at Week 96 to assess eligibility of patient to enter ABX464-108 study if central read results are not available, and add definitions and reporting of SAE/AESI during the study. 9.8.2

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported