Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled Dose-Ranging Study to Evaluate the Safety and Efficacy of CCX140-B in Subjects with Focal Segmental Glomerulosclerosis (FSGS)

Summary

EudraCT number	2017-003021-15
Trial protocol	FR GB PL IT
Global end of trial date	19 February 2020

Results information

Result version number	v1 (current)
This version publication date	10 August 2023
First version publication date	10 August 2023

Trial information

Trial identification

Sponsor protocol code	CL011_140

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03536754
WHO universal trial number (UTN)	-
Other trial identifiers	IND: 134007

Notes:

Sponsors

Sponsor organisation name	ChemoCentryx, Inc.
Sponsor organisation address	850 Maude Avenue, Mountain View, California , United States, 94043
Public contact	Clinical trial disclosure, ChemoCentryx, Inc., clinicaltrials@chemocentryx.com
Scientific contact	Clinical trial disclosure, ChemoCentryx, Inc., clinicaltrials@chemocentryx.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 February 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 February 2020
Global end of trial reached?	Yes
Global end of trial date	19 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

• The primary safety objective of this study is to evaluate the safety and tolerability of CCX140-B in subjects with FSGS with proteinuria.
• The primary efficacy objective of this study is to evaluate the effect of CCX140-B treatment on urinary protein excretion in subjects with FSGS, as assessed by change from baseline in the urine protein to creatinine ratio (UPCR) at Week 12.

Protection of trial subjects:

The study was conducted in accordance with the Declaration of Helsinki and with all applicable laws and regulations of the locale and country where the study was conducted, and in compliance with Good Clinical Practice Guidelines. Only subjects that met all the study inclusion and none of the exclusion criteria were entered in the study. The rationale of the study, procedural details, and investigational goals were explained to each subject, along with potential risks and benefits. Each subject was assured of his/her right to withdraw from the study at any time.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 May 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 14
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	France: 4
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Australia: 2
Country: Number of subjects enrolled	Canada: 8
Country: Number of subjects enrolled	New Zealand: 2
Country: Number of subjects enrolled	United States: 4
Worldwide total number of subjects	46
EEA total number of subjects	25

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)	44
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The recruitment took place in Australia, Canada, France, Italy, New Zealand, Poland, United Kingdom, and in the United States.
The target was to enroll 40 male or female subjects. The first patient was enrolled on 17 May 2018.
A total of 84 subjects were screened; 38 subjects failed screening and 46 subjects were randomized.

Pre-assignment

Screening details:

Eighty-four (84) patients were screened. Screen failure occurred in 38 (45.2%) subjects due to not meeting inclusion or exclusion criteria (35 [41.7%] subjects) and other reasons (3 [3.6%] subjects).

Period 1

Period 1 title	Blinded treatment period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A - Placebo

Arm description: -

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

Dosage and administration details:

Three placebo tablets, taken twice daily (BID), per os, for 84 days (12 weeks)

Arm title	Group B - CCX140-B 5 mg QD

Arm description: -

Arm type	Experimental
Investigational medicinal product name	CCX140-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One 5 mg CCX140-B tablet and 2 placebo tablets in the morning; 3 placebo tablets in the evening; per os, for 84 days.

Arm title	Group C -CCX140-B 10 mg BID

Arm description: -

Arm type	Experimental
Investigational medicinal product name	CCX140-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Two 5 mg CCX140-B tablets and 1 placebo tablet, taken BID; per os, for 84 days.

Arm title	Group D -CCX140-B 15 mg BID
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	CCX140-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Three 5 mg CCX140-B tablets, taken BID; per os, for 84 days.

Number of subjects in period 1	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C -CCX140-B 10 mg BID
Started	12	11	12
Completed	12	11	11
Not completed	0	0	1
Consent withdrawn by subject	-	-	1

Number of subjects in period 1	Group D -CCX140-B 15 mg BID
Started	11
Completed	11
Not completed	0
Consent withdrawn by subject	-

Period 2

Period 2 title	Open-Label Extension
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Open-label extension

Arm description:

Following the 12-week Blinded Treatment Period, all subjects who remained eligible took open-label CCX140-B for an additional 12 weeks (84 consecutive days) at the highest tolerated dose under evaluation, which was determined to be 15 mg BID.

Arm type	Experimental

Investigational medicinal product name	CCX140-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Three 5 mg CCX140-B tablets, orally, BID for 84 days (12 weeks)

Number of subjects in period 2[1]	Open-label extension
Started	43
Completed	42
Not completed	1
Other	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: 46 subjects were randomised in Period A. Only 43 subjects entered the Open-Label Extension.

Baseline characteristics

Reporting groups	
Reporting group title	Group A - Placebo
Reporting group description: -	
Reporting group title	Group B - CCX140-B 5 mg QD
Reporting group description: -	
Reporting group title	Group C -CCX140-B 10 mg BID
Reporting group description: -	
Reporting group title	Group D -CCX140-B 15 mg BID
Reporting group description: -	

Reporting group values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C -CCX140-B 10 mg BID
Number of subjects	12	11	12
Age categorical Units: Subjects			
18-50 years	7	8	10
51-65 years	5	3	1
> 65 years	0	0	1
Gender categorical Units: Subjects			
Female	4	4	5
Male	8	7	7
UPCR at screening			
Urine protein:creatinine ratio (g protein/g creatinine) ≥3.5 Units (g/dL)			
Units: Subjects			
UPCR ≥ 3.5 at screening	3	2	3
UPCR < 3.5 at screening	9	9	9
UPCR at baseline			
Units (g/dL)			
Units: Subjects			
UPCR ≥ 3.5 at baseline	1	1	3
UPCR < 3.5 at baseline	11	10	9
Concomitant use of ACE inhibitor or ARB or aldosterone antagonists Units: Subjects			
Yes	12	10	11
No	0	1	1
Current use of glucocorticoids and/or immunosuppressive medications Units: Subjects			
Yes	7	6	6
No	5	5	6
Concomitant use of glucocorticoids Units: Subjects			
Yes	6	4	4
No	6	7	8
Concomitant use of all calcineurin			

inhibitors combined			
Includes cyclosporin or tacrolimus			
Units: Subjects			
Yes	2	4	3
No	10	7	9
Concomitant use of calcineurin inhibitors cyclosporin Units: Subjects			
Yes	1	1	3
No	11	10	9
Age at screening			
Mean (SD)			
Units: years			
arithmetic mean	46.3	41.7	37.9
standard deviation	± 12.50	± 12.70	± 15.51
UPCR			
urine protein:creatinine ratio			
Units: g protein/g creatinine)			
arithmetic mean	2.19	2.00	2.86
standard deviation	± 1.029	± 1.149	± 2.008
Baseline eGFR (CKD-EPI Creatinine-Cystatin C)			
Baseline estimated Glomerular Filtration Rate (Chronic Kidney Disease Epidemiology Collaboration Creatinine-Cystatin C)			
Units: ml/min/1.73 m 2			
arithmetic mean	72.75	56.18	54.67
standard deviation	± 36.204	± 28.927	± 15.622
Baseline urine MCP-1 creatinine ratio			
Baseline urine MCP-1 creatinine ratio MCP-1: monocyte chemoattractant protein 1			
Units: g protein/g creatinine			
arithmetic mean	453.74	576.41	504.02
standard deviation	± 438.384	± 470.089	± 388.569

Reporting group values	Group D -CCX140-B 15 mg BID	Total	
Number of subjects	11	46	
Age categorical Units: Subjects			
18-50 years	7	32	
51-65 years	3	12	
> 65 years	1	2	
Gender categorical Units: Subjects			
Female	3	16	
Male	8	30	
UPCR at screening			
Urine protein:creatinine ratio (g protein/g creatinine) ≥3.5 Units (g/dL)			
Units: Subjects			
UPCR ≥ 3.5 at screening	3	11	
UPCR < 3.5 at screening	8	35	
UPCR at baseline			
Units (g/dL)			

Units: Subjects			
UPCR ≥ 3.5 at baseline	4	9	
UPCR < 3.5 at baseline	7	37	
Concomitant use of ACE inhibitor or ARB or aldosterone antagonists Units: Subjects			
Yes	10	43	
No	1	3	
Current use of glucocorticoids and/or immunosuppressive medications Units: Subjects			
Yes	6	25	
No	5	21	
Concomitant use of glucocorticoids Units: Subjects			
Yes	5	19	
No	6	27	
Concomitant use of all calcineurin inhibitors combined			
Includes cyclosporin or tacrolimus			
Units: Subjects			
Yes	3	12	
No	8	34	
Concomitant use of calcineurin inhibitors cyclosporin Units: Subjects			
Yes	1	6	
No	10	40	
Age at screening			
Mean (SD)			
Units: years			
arithmetic mean	43.4		
standard deviation	± 13.26	-	
UPCR			
urine protein:creatinine ratio			
Units: g protein/g creatinine)			
arithmetic mean	3.12		
standard deviation	± 2.504	-	
Baseline eGFR (CKD-EPI Creatinine-Cystatin C)			
Baseline estimated Glomerular Filtration Rate (Chronic Kidney Disease Epidemiology Collaboration Creatinine-Cystatin C)			
Units: ml/min/1.73 m 2			
arithmetic mean	61.36		
standard deviation	± 32.265	-	
Baseline urine MCP-1 creatinine ratio			
Baseline urine MCP-1 creatinine ratio MCP-1: monocyte chemoattractant protein 1			
Units: g protein/g creatinine			
arithmetic mean	430.66		
standard deviation	± 325.651	-	

End points

End points reporting groups

Reporting group title	Group A - Placebo
Reporting group description: -	
Reporting group title	Group B - CCX140-B 5 mg QD
Reporting group description: -	
Reporting group title	Group C -CCX140-B 10 mg BID
Reporting group description: -	
Reporting group title	Group D -CCX140-B 15 mg BID
Reporting group description: -	
Reporting group title	Open-label extension
Reporting group description:	
Following the 12-week Blinded Treatment Period, all subjects who remained eligible took open-label CCX140-B for an additional 12 weeks (84 consecutive days) at the highest tolerated dose under evaluation, which was determined to be 15 mg BID.	

Primary: Change from baseline in UPCR at Week 12

End point title	Change from baseline in UPCR at Week 12
End point description:	
Least squared mean ratio of UPCR (Urine protein g:creatinine g) compared to baseline at Week 12 in the ITT population. ITT- Intent to treat	
End point type	Primary
End point timeframe:	
Baseline to Week 12	

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: g protein/g creatinine				
least squares mean (confidence interval 90%)	0.83 (0.69 to 0.99)	1.02 (0.84 to 1.23)	1.12 (0.93 to 1.35)	0.87 (0.72 to 1.05)

Statistical analyses

Statistical analysis title	Mixed-Effects Model for Repeated Measures 1
Comparison groups	Group A - Placebo v Group B - CCX140-B 5 mg QD

Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.1924
Method	Mixed effects model for repeated measure
Parameter estimate	LSM Ratio
Point estimate	1.23
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.95
upper limit	1.6
Variability estimate	Standard error of the mean
Dispersion value	1.171

Statistical analysis title	Mixed-Effects Model for Repeated Measures 2
Comparison groups	Group A - Placebo v Group C -CCX140-B 10 mg BID
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.0612
Method	Mixed effects model for repeated measure
Parameter estimate	LSM Ratio
Point estimate	1.35
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.04
upper limit	1.76
Variability estimate	Standard error of the mean
Dispersion value	1.172

Statistical analysis title	Mixed-Effects Model for Repeated Measures 3
Comparison groups	Group A - Placebo v Group D -CCX140-B 15 mg BID
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.7653
Method	Mixed effects model for repeated measure
Parameter estimate	LSM Ratio
Point estimate	1.05
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.81
upper limit	1.36

Variability estimate	Standard error of the mean
Dispersion value	1.169

Statistical analysis title	Mixed-Effects Model for Repeated Measure 4
Comparison groups	Group A - Placebo v Group D -CCX140-B 15 mg BID v Group B - CCX140-B 5 mg QD v Group C -CCX140-B 10 mg BID
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.1537
Method	Mixed effects model for repeated measure
Parameter estimate	LSM Ratio
Point estimate	1.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.97
upper limit	1.48
Variability estimate	Standard error of the mean
Dispersion value	1.136

Primary: Subject incidence of treatment-emergent AEs (TEAE), TEAEs leading to study withdrawal, and serious adverse events (SAEs)

End point title	Subject incidence of treatment-emergent AEs (TEAE), TEAEs leading to study withdrawal, and serious adverse events (SAEs)[1]

End point description:

TEAEs leading to study withdrawal means study drug discontinuation in this endpoint.

End point type	Primary

End point timeframe:

Baseline to Week 12, and Week 12 to Week 24

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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	12	11
Units: subjects				
TEAEs	10	6	8	7
SAEs	0	0	0	0
TEAEs leading to study withdrawal	0	0	1	0

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: subjects				
TEAEs	24			
SAEs	1			
TEAEs leading to study withdrawal	2			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in Activated Partial Thromboplastin Time

End point title	Change from baseline in Activated Partial Thromboplastin

End point description:

Normal Range: 23.9 - 40.0

End point type	Primary

End point timeframe:

Baseline to Week 12 (double-blind treatment period) and Baseline to Week 24 (open-label extension)

Notes:

[2] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12[3]	10	10	10[4]
Units: second				
arithmetic mean (standard deviation)				
Week 12	2.40 (± 4.259)	2.05 (± 4.396)	2.36 (± 2.614)	1.28 (± 2.508)
Week 24	2.91 (± 4.132)	1.39 (± 3.187)	2.34 (± 6.169)	0.10 (± 3.223)

Notes:

[3] - 11 subjects for Week 24

[4] - 9 subjects for Week 24

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: second				
arithmetic mean (standard deviation)				
Week 12	1.76 (± 4.332)			
Week 24	1.76 (± 4.332)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma alanine aminotransferase

End point title	Change from baseline in plasma alanine aminotransferase[5]

End point description:

Normal Range: 6 - 41 U/L

End point type	Primary

End point timeframe:

Baseline to Week 12 and Baseline to Week 24

Notes:

[5] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: U/L				
arithmetic mean (standard deviation)	0.5 (± 2.70)	0.8 (± 5.22)	0.3 (± 3.29)	-1.8 (± 2.95)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: U/L				
arithmetic mean (standard deviation)	0.0 (± 3.65)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma alkaline phosphatase

End point title	Change from baseline in plasma alkaline phosphatase[6]

End point description:

End point type	Primary

End point timeframe:

Baseline to Week 12
Baseline to Week 24

Notes:

[6] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: U/L				
arithmetic mean (standard deviation)	10.2 (± 7.08)	-1.0 (± 11.59)	0.7 (± 15.86)	-1.9 (± 9.45)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: U/L				
arithmetic mean (standard deviation)	2.3 (± 12.16)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma amylase

End point title	Change from baseline in plasma amylase[7]

End point description:

Normal range: 22-123 U/L

End point type	Primary

End point timeframe:

From Baseline to Week 12
From baseline to Week 24

Notes:

[7] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: U/L				
arithmetic mean (standard deviation)	3.1 (± 16.11)	8.9 (± 18.30)	5.0 (± 24.56)	3.9 (± 23.19)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: U/L				
arithmetic mean (standard deviation)	5.2 (± 20.09)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma aspartate aminotransferase

End point title	Change from baseline in plasma aspartate aminotransferase[8]

End point description:

Normal range : 9-34 U/L

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[8] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: U/L				
arithmetic mean (standard deviation)	18.3 (± 6.17)	-0.4 (± 4.60)	-3.5 (± 7.71)	-3.2 (± 3.07)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: U/L				
arithmetic mean (standard deviation)	-1.7 (± 5.25)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma bicarnonate

End point title	Change from baseline in plasma bicarnonate[9]

End point description:

Normal range: 21-33 mmol/L

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[9] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mmol/L				
arithmetic mean (standard deviation)	0.5 (± 3.45)	-0.4 (± 3.24)	0.9 (± 3.59)	-0.6 (± 2.83)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mmol/L				
arithmetic mean (standard deviation)	0.1 (± 3.24)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma bilirubin

End point title	Change from baseline in plasma bilirubin[10]

End point description:

Normal range: 0.1-1.10 mg/dL

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[10] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	0.044 (± 0.1985)	-0.006 (± 0.2796)	0.160 (± 0.2381)	-0.012 (± 0.1519)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				
arithmetic mean (standard deviation)	0.050 (± 0.2263)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma C reactive protein

End point title	Change from baseline in plasma C reactive protein[11]

End point description:

Normal range: 0.0-3.0 mg/L

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[11] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/L				
arithmetic mean (standard deviation)	1.200 (± 3.1597)	2.144 (± 8.5528)	-1.000 (± 4.6448)	-1.444 (± 3.8014)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			

Units: mg/L				
arithmetic mean (standard deviation)	0.260 (± 5.4276)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma calcium

End point title	Change from baseline in plasma calcium[12]

End point description:

Normal range: 8.5-10.5 mg/dL

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[12] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	0.18 (± 0.387)	0.20 (± 0.427)	0.17 (± 0.498)	-0.01 (± 0.454)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				
arithmetic mean (standard deviation)	0.14 (± 0.434)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma chloride

End point title	Change from baseline in plasma chloride[13]

End point description:

Normal range: 95-110 mmol/L

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[13] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mmol/L				
arithmetic mean (standard deviation)	-0.5 (± 2.70)	0.9 (± 1.79)	-0.8 (± 3.31)	3.2 (± 2.33)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mmol/L				
arithmetic mean (standard deviation)	0.6 (± 2.97)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma cholesterol

End point title	Change from baseline in plasma cholesterol[14]

End point description:

Normal range: 100-200 mg/dL

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[14] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	-2.7 (± 31.11)	-2.0 (± 27.67)	18.9 (± 48.17)	-43.0 (± 64.17)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				
arithmetic mean (standard deviation)	-5.6 (± 47.99)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma creatine kinase

End point title	Change from baseline in plasma creatine kinase[15]

End point description:

Normal range: 23-210 U/L

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[15] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: U/L				
arithmetic mean (standard deviation)	21.2 (± 39.65)	18.1 (± 59.20)	-19.5 (± 89.93)	14.2 (± 206.95)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: U/L				
arithmetic mean (standard deviation)	11.9 (± 89.15)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma creatinine

End point title	Change from baseline in plasma creatinine[16]

End point description:

Normal range: 0.62-1.44 mg/dL

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[16] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: mg/dL				
arithmetic mean (standard deviation)	0.060 (± 0.1437)	0.033 (± 0.2461)	0.115 (± 0.2186)	0.147 (± 0.3790)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				
arithmetic mean (standard deviation)	0.161 (± 0.3926)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma cystatin C

End point title	Change from baseline in plasma cystatin C[17]

End point description:

Normal range: 0.53-0.95 mg/L

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[17] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/L				
arithmetic mean (standard deviation)	0.114 (± 0.1838)	0.104 (± 0.1074)	0.093 (± 0.2896)	0.018 (± 0.2198)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/L				
arithmetic mean (standard deviation)	0.087 (± 0.2436)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma direct bilirubin

End point title	Change from baseline in plasma direct bilirubin[18]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[18] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	0.011 (± 0.0396)	0.008 (± 0.0316)	0.005 (± 0.0497)	-0.005 (± 0.0254)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			

Units: mg/dL				
arithmetic mean (standard deviation)	0.004 (± 0.0373)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma glucose

End point title	Change from baseline in plasma glucose[19]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[19] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	-5.3 (± 15.11)	1.1 (± 10.58)	1.5 (± 16.91)	-6.2 (± 14.07)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: mg/dL				
arithmetic mean (standard deviation)	-0.9 (± 14.27)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma HDL cholesterol

End point title	Change from baseline in plasma HDL cholesterol[20]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[20] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	0.8 (± 5.75)	-2.3 (± 12.95)	2.1 (± 20.41)	2.4 (± 9.65)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				
arithmetic mean (standard deviation)	0.7 (± 9.39)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma indirect bilirubin

End point title	Change from baseline in plasma indirect bilirubin[21]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[21] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	0.043 (± 0.1033)	-0.009 (± 0.0919)	0.054 (± 0.2866)	-0.043 (± 0.1572)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				
arithmetic mean (standard deviation)	0.046 (± 0.1947)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma LDL cholesterol

End point title	Change from baseline in plasma LDL cholesterol[22]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[22] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	10	10
Units: mg/dL				
arithmetic mean (standard deviation)	12.2 (± 19.97)	-2.8 (± 11.36)	8.0 (± 24.86)	-8.9 (± 37.78)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: mg/dL				
arithmetic mean (standard deviation)	-5.0 (± 37.61)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in lactate dehydrogenase

End point title	Change from baseline in lactate dehydrogenase[23]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[23] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: U/L				
arithmetic mean (standard deviation)	-10.2 (± 25.67)	-26.4 (± 69.73)	-14.5 (± 26.09)	5.1 (± 27.15)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: U/L				
arithmetic mean (standard deviation)	-12.0 (± 41.83)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma pancreatic lipase

End point title	Change from baseline in plasma pancreatic lipase[24]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[24] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: U/L				
arithmetic mean (standard deviation)	3.6 (± 9.71)	8.1 (± 24.14)	-5.2 (± 9.81)	24.5 (± 51.50)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: U/L				
arithmetic mean (standard deviation)	9.0 (± 50.27)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma magnesium

End point title	Change from baseline in plasma magnesium[25]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[25] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	0.10 (± 0.148)	0.02 (± 0.140)	-0.02 (± 0.240)	0.09 (± 0.321)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				

arithmetic mean (standard deviation)	0.01 (± 0.199)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma phospate

End point title	Change from baseline in plasma phospate[26]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[26] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	0.33 (± 0.609)	0.16 (± 0.423)	0.15 (± 0.596)	0.04 (± 0.803)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				
arithmetic mean (standard deviation)	0.04 (± 0.580)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma potassium

End point title	Change from baseline in plasma potassium[27]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[27] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	11	10
Units: mmol/L				
arithmetic mean (standard deviation)	0.09 (± 0.327)	0.12 (± 0.232)	-0.09 (± 0.305)	0.23 (± 0.789)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	38			
Units: mmol/L				
arithmetic mean (standard deviation)	0.00 (± 0.514)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma protein

End point title	Change from baseline in plasma protein[28]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[28] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: g/dL				
arithmetic mean (standard deviation)	0.17 (± 0.320)	0.05 (± 0.305)	-0.11 (± 0.575)	-0.09 (± 0.396)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: g/dL				
arithmetic mean (standard deviation)	0.00 (± 0.515)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in prothrombin intl. normalised ratio

End point title	Change from baseline in prothrombin intl. normalised ratio[29]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[29] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	10	10
Units: N/A				
arithmetic mean (standard deviation)	0.03 (± 0.210)	0.01 (± 0.160)	0.10 (± 0.141)	0.01 (± 0.088)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: N/A				
arithmetic mean (standard deviation)	0.08 (± 0.387)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in prothrombin time

End point title	Change from baseline in prothrombin time[30]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[30] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	10	10
Units: second				
arithmetic mean (standard deviation)	0.48 (± 1.566)	0.07 (± 1.561)	0.69 (± 1.268)	0.33 (± 0.736)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: second				
arithmetic mean (standard deviation)	0.78 (± 3.445)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma sodium

End point title	Change from baseline in plasma sodium[31]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[31] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mmol/L				
arithmetic mean (standard deviation)	0.0 (± 2.22)	1.8 (± 3.89)	0.9 (± 3.59)	2.5 (± 5.05)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mmol/L				
arithmetic mean (standard deviation)	1.0 (± 3.46)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma triglycerides

End point title	Change from baseline in plasma triglycerides[32]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[32] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	16.6 (± 123.84)	5.7 (± 51.48)	-16.5 (± 25.80)	-23.2 (± 123.79)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				

arithmetic mean (standard deviation)	-2.6 (± 80.08)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma urate

End point title	Change from baseline in plasma urate[33]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[33] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	0.51 (± 0.485)	0.04 (± 1.107)	-0.28 (± 0.877)	-0.08 (± 0.926)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				
arithmetic mean (standard deviation)	-0.05 (± 1.040)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in plasma urea nitrogen

End point title	Change from baseline in plasma urea nitrogen[34]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[34] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	2.8 (± 3.65)	-2.6 (± 4.18)	3.6 (± 5.95)	1.1 (± 11.42)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	41			
Units: mg/dL				
arithmetic mean (standard deviation)	2.3 (± 6.15)			

Statistical analyses

No statistical analyses for this end point

Primary: Changes for baseline in basophils

End point title	Changes for baseline in basophils[35]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[35] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: 10^9/L				
arithmetic mean (standard deviation)	0.02 (± 0.058)	0.03 (± 0.047)	0.02 (± 0.60)	-0.03 (± 0.048)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: 10^9/L				
arithmetic mean (standard deviation)	0.02 (± 0.063)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline basophils/leukocytes

End point title	Change from baseline basophils/leukocytes[36]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[36] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: N/A				
arithmetic mean (standard deviation)	0.08 (± 0.389)	-0.01 (± 0.459)	0.18 (± 0.547)	-0.13 (± 0.419)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: N/A				
arithmetic mean (standard deviation)	0.16 (± 0.433)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in eosinophils

End point title	Change from baseline in eosinophils[37]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[37] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	12	11
Units: 10^9/L				
arithmetic mean (standard deviation)	0.01 (± 0.108)	0.01 (± 0.122)	0.00 (± 0.184)	0.01 (± 0.099)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: 10^9/L				
arithmetic mean (standard deviation)	0.03 (± 0.162)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in Eosinophils/Leukocytes

End point title	Change from baseline in Eosinophils/Leukocytes[38]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[38] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: N/A				
arithmetic mean (standard deviation)	0.32 (± 1.375)	0.09 (± 0.984)	-0.02 (± 2.245)	0.33 (± 1.430)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: N/A				
arithmetic mean (standard deviation)	0.27 (± 1.922)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in Erythrocyte Mean Corpuscular HGB Concentration

End point title	Change from baseline in Erythrocyte Mean Corpuscular HGB Concentration[39]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[39] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: g/dL				
arithmetic mean (standard deviation)	-0.20 (± 0.603)	-0.18 (± 0.778)	-0.24 (± 0.439)	-0.16 (± 0.556)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			

Units: g/dL				
arithmetic mean (standard deviation)	-0.28 (± 0.891)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in Erythrocyte Mean Corpuscular Hemoglobin

End point title	Change from baseline in Erythrocyte Mean Corpuscular Hemoglobin[40]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[40] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: picogram(s)				
arithmetic mean (standard deviation)	-0.2 (± 0.58)	-0.3 (± 0.47)	-0.5 (± 0.82)	0.0 (± 0.82)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: picogram(s)				
arithmetic mean (standard deviation)	-0.1 (± 0.80)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in Erythrocyte Mean Corpuscular Volume

End point title	Change from baseline in Erythrocyte Mean Corpuscular

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[41] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: fL				
arithmetic mean (standard deviation)	-0.21 (± 1.472)	-0.02 (± 2.093)	-0.33 (± 1.251)	0.03 (± 1.931)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: fL				
arithmetic mean (standard deviation)	0.44 (± 1.801)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in erythrocytes

End point title	Change from baseline in erythrocytes[42]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[42] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: 10^12/L				
arithmetic mean (standard deviation)	-0.004 (± 0.2946)	0.055 (± 0.2211)	0.010 (± 0.2326)	-0.55 (± 0.1761)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: 10^12/L				
arithmetic mean (standard deviation)	-0.003 (± 0.2968)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in hematocrit

End point title	Change from baseline in hematocrit[43]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[43] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: NA				
arithmetic mean (standard deviation)	-0.3 (± 2.34)	0.5 (± 2.11)	-0.1 (± 2.26)	-0.8 (± 1.55)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: NA				

arithmetic mean (standard deviation)	0.2 (± 2.61)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in hemoglobin

End point title	Change from baseline in hemoglobin[44]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[44] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: g/dL				
arithmetic mean (standard deviation)	-0.12 (± 0.802)	0.13 (± 0.588)	-0.10 (± 0.784)	-0.25 (± 0.488)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: g/dL				
arithmetic mean (standard deviation)	-0.07 (± 0.923)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in leukocytes

End point title	Change from baseline in leukocytes[45]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[45] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: 10^3/microlitre				
arithmetic mean (standard deviation)	-0.98 (± 1.915)	0.45 (± 1.012)	0.37 (± 1.819)	-0.09 (± 1.928)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: 10^3/microlitre				
arithmetic mean (standard deviation)	-0.09 (± 1.711)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in lymphocytes

End point title	Change from baseline in lymphocytes[46]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[46] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: 10^3/L				
arithmetic mean (standard deviation)	-0.080 (± 0.2152)	0.122 (± 0.3541)	0.099 (± 0.4865)	0.194 (± 0.9257)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: 10^3/L				
arithmetic mean (standard deviation)	0.161 (± 0.4165)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in lymphocytes/leukocytes

End point title	Change from baseline in lymphocytes/leukocytes[47]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[47] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: N/A				
arithmetic mean (standard deviation)	2.51 (± 5.052)	0.06 (± 6.287)	-0.99 (± 8.132)	1.52 (± 7.013)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			

Units: N/A				
arithmetic mean (standard deviation)	2.61 (± 7.099)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in monocytes/leukocytes

End point title	Change from baseline in monocytes/leukocytes[48]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[48] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: N/A				
arithmetic mean (standard deviation)	1.38 (± 1.641)	0.25 (± 2.056)	0.99 (± 3.022)	0.56 (± 1.532)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: N/A				
arithmetic mean (standard deviation)	-0.21 (± 2.262)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in neutrophils

End point title	Change from baseline in neutrophils[49]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[49] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: 10^3/L				
arithmetic mean (standard deviation)	-0.954 (± 1.6290)	0.255 (± 1.1041)	0.137 (± 1.6023)	-0.289 (± 1.4171)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: 10^3/L				
arithmetic mean (standard deviation)	-0.281 (± 1.5104)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in neutrophils/leukocytes

End point title	Change from baseline in neutrophils/leukocytes[50]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[50] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: N/A				
arithmetic mean (standard deviation)	-4.28 (± 5.941)	-0.39 (± 6.548)	-0.16 (± 8.247)	-2.28 (± 7.230)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: N/A				
arithmetic mean (standard deviation)	-2.84 (± 7.830)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in platelets

End point title	Change from baseline in platelets[51]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[51] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	11	10
Units: 10^9/L				
arithmetic mean (standard deviation)	5.2 (± 31.68)	26.2 (± 30.10)	4.8 (± 28.72)	0.9 (± 27.65)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: 10^9/L				

arithmetic mean (standard deviation)	19.1 (± 54.30)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in reticulocytes/erythorcytes

End point title	Change from baseline in reticulocytes/erythorcytes[52]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[52] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	10
Units: N/A				
arithmetic mean (standard deviation)	-0.08 (± 0.626)	-0.11 (± 0.554)	-0.30 (± 0.615)	-0.12 (± 0.290)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: N/A				
arithmetic mean (standard deviation)	-0.14 (± 0.536)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in urine albumin

End point title	Change from baseline in urine albumin[53]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[53] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	1.117 (± 118.7664)	-19.044 (± 119.7149)	-8.455 (± 53.9332)	-35.964 (± 178.9164)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: mg/dL				
arithmetic mean (standard deviation)	-28.433 (± 107.8847)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in urine creatinine

End point title	Change from baseline in urine creatinine[54]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[54] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	10.65 (± 35.931)	-11.67 (± 33.423)	-15.37 (± 30.920)	25.30 (± 84.654)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: mg/dL				
arithmetic mean (standard deviation)	-6.96 (± 31.530)			

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in urine protein

End point title	Change from baseline in urine protein[55]

End point description:

End point type	Primary

End point timeframe:

From baseline to Week 12
From baseline to Week 24

Notes:

[55] - 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: Due to the small sample size and abbreviated summary of data no per-protocol analyses was carried out

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mg/dL				
arithmetic mean (standard deviation)	-19.3 (± 139.96)	-8.9 (± 134.17)	-9.0 (± 80.51)	-80.6 (± 230.57)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	42			

Units: mg/dL				
arithmetic mean (standard deviation)	-35.1 (± 144.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in estimated glomerular filtration rate (eGFR) at Week 12 and Week 24

End point title	Change from baseline in estimated glomerular filtration rate (eGFR) at Week 12 and Week 24

End point description:

Change from baseline in eGFR calculated by the CKD-EPI Cystatin C equation, CKD-EPI Creatinine equation, CKD-EPI Creatinine-Cystatin C equation and MDRD Creatinine equation at Weeks 12 and 24.

CKD-EPI: Chronic Kidney Disease Epidemiology Collaboration; MDRD: Modification of Diet in Renal Disease

Open label extension covers Baseline to Week 13 and Baseline to Week 24

End point type	Secondary

End point timeframe:

Baseline to Week 12
Baseline to Week 24

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: mL/min/1.73m2				
arithmetic mean (standard deviation)				
CKD-EPI Cystatin C equation Week 12	-4.9 (± 11.74)	-3.1 (± 3.91)	-1.6 (± 8.61)	0.2 (± 9.51)
CKD-EPI Cystatin C equation Week 24	-0.8 (± 6.63)	-3.2 (± 10.40)	-1.3 (± 9.69)	-3.2 (± 9.60)
CKD-EPI Creatinine equation Week 12	-3.0 (± 6.47)	-4.2 (± 11.50)	-3.9 (± 5.74)	-4.8 (± 9.68)
CKD-EPI Creatinine equation Week 24	-3.1 (± 5.74)	-8.2 (± 9.89)	-5.3 (± 10.59)	-2.0 (± 8.29)
CKD-EPI Creatinine-Cystatin C equation Week 12	-5.3 (± 8.92)	-3.5 (± 5.61)	-2.6 (± 6.53)	-2.8 (± 8.57)
CKD-EPI Creatinine-Cystatin C equation Week 24	-2.4 (± 5.24)	-5.5 (± 9.20)	-3.2 (± 9.18)	-2.8 (± 7.93)
MDRD Creatinine equation Week 12	-4.7 (± 10.82)	-5.1 (± 13.75)	-4.6 (± 6.23)	-6.7 (± 14.03)
MDRD Creatinine equation Week 24	-4.5 (± 11.12)	-8.8 (± 12.85)	-5.9 (± 10.05)	-4.0 (± 10.77)

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	43			

Units: mL/min/1.73m2				
arithmetic mean (standard deviation)				
CKD-EPI Cystatin C equation Week 12	-1.7 (± 9.49)			
CKD-EPI Cystatin C equation Week 24	-2.0 (± 8.86)			
CKD-EPI Creatinine equation Week 12	-4.7 (± 9.68)			
CKD-EPI Creatinine equation Week 24	-4.7 (± 8.80)			
CKD-EPI Creatinine-Cystatin C equation Week 12	-3.2 (± 8.43)			
CKD-EPI Creatinine-Cystatin C equation Week 24	-3.4 (± 7.82)			
MDRD Creatinine equation Week 12	-5.6 (± 13.76)			
MDRD Creatinine equation Week 24	-5.8 (± 10.95)			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects achieving complete or partial renal remission at Week 12 and Week 24

End point title	Proportion of subjects achieving complete or partial renal remission at Week 12 and Week 24

End point description:

1. Proportion of subjects achieving complete renal remission by the following definition at Weeks 12 and 24
o Reduction in UPCR to <0.3 g/g
o Serum albumin within normal range (for subjects with abnormal serum creatinine levels at baseline, return to normal levels for that age group; for subjects with normal serum creatinine levels at baseline, final value within 20% of baseline levels)

2. Proportion of subjects achieving partial remission defined as UPCR reduction of ≥50% from baseline and UPCR <3.5 g/g (definition 1), assessed at Weeks 12 and 24

3. Proportion of subjects achieving partial remission defined Decrease in UPCR to less than 1.5 g/g and at least a 40% reduction in proteinuria from baseline (definition 2), assessed at Weeks 12 and 24

End point type	Secondary

End point timeframe:

Endpoint at Week 12
Endpoint at Week 24

End point values	Group A - Placebo	Group B - CCX140-B 5 mg QD	Group C - CCX140-B 10 mg BID	Group D - CCX140-B 15 mg BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	11	11
Units: subjects				
Complete renal remission	0	0	0	0
Partial remission (definition 1)	1	0	0	1
Partial remission (definition 2)	0	0	0	0

End point values	Open-label extension			
Subject group type	Reporting group			
Number of subjects analysed	43			
Units: subjects				
Complete renal remission	0			
Partial remission (definition 1)	4			
Partial remission (definition 2)	6			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From Baseline to Week 24	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups	
Reporting group title	All CCX140-B treated - overall study

Reporting group description:

All the patients who received CCX140-B at least once during the double-blind and/or the open-label extension are included. One patient who received the placebo treatment in the double-blind period and did not enter in the open-label extenstion is not included in this reporting group. This patient did not experience any adverse event.

Serious adverse events	All CCX140-B treated - overall study		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 45 (2.22%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Renal and urinary disorders			
Acute kidney injury	Additional description: The SAE acute kidney injury was considered Possibly Related by the Investigator but not by the Sponsor.		
subjects affected / exposed	1 / 45 (2.22%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Dermo-hypodermitis			
subjects affected / exposed	1 / 45 (2.22%)		
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	All CCX140-B treated - overall study		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 45 (73.33%)		
Investigations			
Blood creatinine increased			
subjects affected / exposed	4 / 45 (8.89%)		
occurrences (all)	4		
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 45 (11.11%)		
occurrences (all)	11		
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	8 / 45 (17.78%)		
occurrences (all)	9		
Fatigue			
subjects affected / exposed	4 / 45 (8.89%)		
occurrences (all)	5		
Oedema			
subjects affected / exposed	3 / 45 (6.67%)		
occurrences (all)	3		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 45 (8.89%)		
occurrences (all)	5		
Nausea			
subjects affected / exposed	3 / 45 (6.67%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 45 (6.67%)		
occurrences (all)	3		
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	3 / 45 (6.67%)		
occurrences (all)	5		

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 45 (11.11%)		
occurrences (all)	5		
Muscle spasms			
subjects affected / exposed	4 / 45 (8.89%)		
occurrences (all)	7		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 45 (8.89%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	7 / 45 (15.56%)		
occurrences (all)	10		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 December 2017	An update was made to the guidelines for dose modification.
18 January 2018	1. Stratification criteria was updated. 2. The inclusion and exclusion criteria were updated. 3. The secondary objective to evaluate the effect of CCX140-B on renal function was updated 4. The table describing the dose modification guidelines for single subjects was moved to the study design section of the protocol. 5. Screening investigations were clarified. 6. A clinical safety laboratory assessment was added. 10. The pregnancies, special situation, and serious AE (SAE) reporting instructions were updated.
15 February 2018	1. ACTG-BPNST Screening assessment were updated. 2. Changes were made to the dose modification guidelines 3. The inclusion criterion for female subjects of childbearing potential was updated. 4. The exclusion criteria were updated. 5. The timeframe for recording of prior medications was updated. 6. It was clarified that the time of blood collection should be recorded for all PK sample blood draws. 7. Safety assessments during the Early Termination Visit were updated.
29 October 2018	1. The analysis of the primary efficacy objective was clarified to be at Week 12. 2. A secondary objective to evaluate the effect of CCX140-B treatment was added. 3. The inclusion criterion for female subjects of childbearing potential was updated. 4. The exclusion criteria was updated. 5. Secondary efficacy endpoints were updated 6. The Blinded Treatment Period, the Open-Label Extension and the Follow-up Period were clarified. 7. A 24-hour urine collection schedule and investigations were added and clarified. 8. The timing of PK blood sample collection was clarified. 9. It was clarified that following the 12-week Blinded Treatment Period, the study would evaluate up to 24 weeks of treatment with CCX140-B. 10. The dose modification guidelines for clarified. 11. Potentially prohibited medications taken prior to enrolment that were to be recorded were specified. 12. Language describing the usage of local laboratories was removed. 13. Study procedures were added. 14. Reminders for discontinuing subjects after the completion of all study procedures were added. 15. The collection of whole blood for the assessment of elimination upon discontinuation of treatment was clarified. 16. Efficacy assessment was clarified. 17. The clinical safety laboratory assessments were updated. 18. Sample collection for PD measurement was clarified. 19. An exploratory efficacy endpoint was updated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported