Clinical trial results:
A multi-center, randomized, double-blind, parallel-group, 20-week dose-finding study to evaluate efficacy, safety, and tolerability of XXB750 in patients with resistant hypertension

Summary

EudraCT number	2021-005738-41
Trial protocol	ES FR CZ SK IT NL DE BG
Global end of trial date	27 August 2024

Results information

Result version number	v2 (current)
This version publication date	28 January 2026
First version publication date	11 September 2025
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	CXXB750B12201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05562934
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Lichtstrasse 35, Basel, Switzerland, 4056
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.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	27 August 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy and dose-response relationship of XXB750 30 mg subcutaneous (SC) every four weeks (q4w), 60 mg SC q4w, 120 mg SC q4w, and 240 mg SC q4w compared to placebo in reducing the mean 24 hours ambulatory systolic blood pressure (mean 24hr SBP) from baseline to Week 12.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 November 2022
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	United States: 56
Country: Number of subjects enrolled	Australia: 7
Country: Number of subjects enrolled	Slovakia: 8
Country: Number of subjects enrolled	Spain: 13
Country: Number of subjects enrolled	Japan: 14
Country: Number of subjects enrolled	France: 8
Country: Number of subjects enrolled	Taiwan: 11
Country: Number of subjects enrolled	Poland: 12
Country: Number of subjects enrolled	United Kingdom: 9
Country: Number of subjects enrolled	Bulgaria: 14
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Austria: 2
Country: Number of subjects enrolled	China: 11
Country: Number of subjects enrolled	Italy: 8
Country: Number of subjects enrolled	Czechia: 3
Worldwide total number of subjects	189
EEA total number of subjects	81

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)	112
From 65 to 84 years	75
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Participants took part in 135 investigative sites in 16 countries.

Pre-assignment

Screening details:

The study consisted of a screening period of approximately 7 days.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo subcutaneous (s.c) every 4 weeks, total of 3 doses.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo subcutaneous every 4 weeks, total of 3 doses.

Arm title	XXB750 30 mg

Arm description:

XXB750 30 mg s.c every 4 weeks, total of 3 doses.

Arm type	Experimental
Investigational medicinal product name	XXB750
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

XXB750 30 mg subcutaneous every 4 weeks, total of 3 doses.

Arm title	XXB750 60 mg

Arm description:

XXB750 60 mg s.c every 4 weeks, total of 3 doses.

Arm type	Experimental
Investigational medicinal product name	XXB750
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

XXB750 60 mg subcutaneous every 4 weeks, total of 3 doses.

Arm title	XXB750 120 mg

Arm description:

XXB750 120 mg s.c every 4 weeks, total of 3 doses.

Arm type	Experimental
Investigational medicinal product name	XXB750
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

XXB750 120 mg subcutaneous every 4 weeks, total of 3 doses.

Arm title	XXB750 120 mg/240 mg

Arm description:

XXB750 120 mg s.c at the randomization visit followed by 240 mg s.c at Week 4 and Week 8.

Arm type	Experimental
Investigational medicinal product name	XXB750
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

XXB750 120 mg subcutaneous (s.c.) at the randomization visit followed by 240 mg s.c at Week 4 and Week 8.

Number of subjects in period 1	Placebo	XXB750 30 mg	XXB750 60 mg
Started	42	32	36
Completed	42	30	35
Not completed	0	2	1
Consent withdrawn by subject	-	-	1
Adverse events	-	2	-
Lost to follow-up	-	-	-
Protocol deviation	-	-	-

Number of subjects in period 1	XXB750 120 mg	XXB750 120 mg/240 mg
Started	37	42
Completed	35	38
Not completed	2	4
Consent withdrawn by subject	1	-
Adverse events	-	2

Lost to follow-up	-	1
Protocol deviation	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo subcutaneous (s.c) every 4 weeks, total of 3 doses.	
Reporting group title	XXB750 30 mg
Reporting group description:	
XXB750 30 mg s.c every 4 weeks, total of 3 doses.	
Reporting group title	XXB750 60 mg
Reporting group description:	
XXB750 60 mg s.c every 4 weeks, total of 3 doses.	
Reporting group title	XXB750 120 mg
Reporting group description:	
XXB750 120 mg s.c every 4 weeks, total of 3 doses.	
Reporting group title	XXB750 120 mg/240 mg
Reporting group description:	
XXB750 120 mg s.c at the randomization visit followed by 240 mg s.c at Week 4 and Week 8.	

Reporting group values	Placebo	XXB750 30 mg	XXB750 60 mg
Number of subjects	42	32	36
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	26	23	18
From 65-84 years	16	8	18
85 years and over	0	1	0
Age Continuous Units: years			
arithmetic mean	60.14	58.53	63.44
standard deviation	± 10.862	± 11.565	± 10.191
Sex: Female, Male Units: participants			
Female	13	8	6
Male	29	24	30
Race/Ethnicity, Customized Units: Subjects			
Black Or African American	6	7	4
White	27	16	24
Asian	8	5	6
Other	1	4	2

Reporting group values	XXB750 120 mg	XXB750 120 mg/240 mg	Total
Number of subjects	37	42	189
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	18	27	112
From 65-84 years	19	14	75
85 years and over	0	1	2
Age Continuous Units: years			
arithmetic mean	62.41	60.64	
standard deviation	± 11.642	± 10.085	-
Sex: Female, Male Units: participants			
Female	18	13	58
Male	19	29	131
Race/Ethnicity, Customized Units: Subjects			
Black Or African American	4	6	27
White	24	25	116
Asian	8	10	37
Other	1	1	9

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo subcutaneous (s.c) every 4 weeks, total of 3 doses.	
Reporting group title	XXB750 30 mg
Reporting group description:	
XXB750 30 mg s.c every 4 weeks, total of 3 doses.	
Reporting group title	XXB750 60 mg
Reporting group description:	
XXB750 60 mg s.c every 4 weeks, total of 3 doses.	
Reporting group title	XXB750 120 mg
Reporting group description:	
XXB750 120 mg s.c every 4 weeks, total of 3 doses.	
Reporting group title	XXB750 120 mg/240 mg
Reporting group description:	
XXB750 120 mg s.c at the randomization visit followed by 240 mg s.c at Week 4 and Week 8.	

Primary: Dose-response (DR) relationship of XXB750 with respect to change from baseline in Systolic Blood Pressure (SBP) 24 hours

End point title	Dose-response (DR) relationship of XXB750 with respect to change from baseline in Systolic Blood Pressure (SBP) 24 hours
End point description:	
To evaluate the efficacy and dose-response relationship of different doses of XXB750 compared to placebo in reducing the mean 24 hours ambulatory systolic blood pressure from baseline at Week 12. Automated arterial BP determinations and pulse rate readings were made with Microlife Watch BP Office 2G, an automated digital BP device. The primary outcome measure was evaluated using an optimally weighted contrast test following the Multiple Comparison Procedure-Modeling (MCP-MOD) methodology. There were five candidate models to capture the shape of the dose-response relationship for XXB750 at Week 12 endpoint. The outcome for the single best candidate model is shown in the Statistical Analysis section.	
End point type	Primary
End point timeframe:	
Baseline, Week 12	

End point values	Placebo	XXB750 30 mg	XXB750 60 mg	XXB750 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	25	30	32
Units: mmHg				
least squares mean (confidence interval 95%)	-5.77 (-10.74 to -1.12)	-6.41 (-10.15 to -2.85)	-6.63 (-10.40 to -3.53)	-6.66 (-12.57 to -3.16)

End point values	XXB750 120 mg/240 mg			

Subject group type	Reporting group			
Number of subjects analysed	36			
Units: mmHg				
least squares mean (confidence interval 95%)	-5.40 (-9.58 to -0.36)			

Statistical analyses

Statistical analysis title	SBP
Comparison groups	Placebo v XXB750 30 mg v XXB750 60 mg v XXB750 120 mg v XXB750 120 mg/240 mg
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5651 [1]
Method	Multiple Comparisons Procedure-MOD

Notes:

[1] - Single best candidate model is the one with the lowest adjusted p-value of the 5 candidate models

Secondary: Change from baseline in SBP 24 hours of average of Week 9 and Week 12 (difference between highest XXB750 dose and placebo)

End point title	Change from baseline in SBP 24 hours of average of Week 9 and Week 12 (difference between highest XXB750 dose and placebo)[2]

End point description:

To evaluate the treatment effect of the highest XXB750 dose versus placebo in the dosing interval average of ambulatory SBP as assessed by average of mean 24 hours SBP measured at week 9 and week 12. Automated arterial BP determinations and pulse rate readings were made with Microlife Watch BP Office 2G, an automated digital BP device.

End point type	Secondary

End point timeframe:

Baseline, Week 9 and Week 12

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: the outcome is specific for these arms

End point values	Placebo	XXB750 120 mg/240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	38		
Units: mmHg				
least squares mean (standard error)	-5.77 (± 2.13)	-4.62 (± 2.21)		

Statistical analyses

Statistical analysis title	SBP
Comparison groups	Placebo v XXB750 120 mg/240 mg

Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.7108
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	7.18

Secondary: Change from baseline in SBP 24 hours at Week 12 (difference between highest XXB750 dose and placebo)

End point title	Change from baseline in SBP 24 hours at Week 12 (difference between highest XXB750 dose and placebo)[3]

End point description:

To evaluate the treatment effect of the highest XXB750 dose versus placebo in reducing the mean 24 hours SBP from baseline to Week 12. Automated arterial BP determinations and pulse rate readings were made with Microlife Watch BP Office 2G, an automated digital BP device.

End point type	Secondary

End point timeframe:

Baseline, Week 12

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: the outcome is specific for these arms

End point values	Placebo	XXB750 120 mg/240 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	36		
Units: mmHg				
least squares mean (standard error)	-6.01 (± 2.42)	-4.64 (± 2.49)		

Statistical analyses

Statistical analysis title	SBP
Comparison groups	Placebo v XXB750 120 mg/240 mg
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6955
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	1.37

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.48
upper limit	8.21

Secondary: The model-based estimated percentage of participants achieving blood pressure (BP) control

End point title	The model-based estimated percentage of participants achieving blood pressure (BP) control

End point description:

To evaluate the percentage of participants achieving ambulatory BP control defined as mean 24 hours SBP <130 mmHg and mean 24 hours DBP < 80 mmHg with respect to the dose-response relationship of the four XXB750 dose level groups compared to placebo at week 12. Automated arterial BP determinations and pulse rate readings were made with Microlife Watch BP Office 2G, an automated digital BP device. Percentage of participants is derived from dose response analysis, using generalized MCP-Mod methodology for binary data.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	XXB750 30 mg	XXB750 60 mg	XXB750 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	25	30	32
Units: percentage				
number (not applicable)	13.2	15.0	17.7	22.0

End point values	XXB750 120 mg/240 mg			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: percentage				
number (not applicable)	25.9			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Adverse events were reported from first dose of study treatment until end of study treatment plus follow up period, up to a maximum duration of approximately 20 weeks.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups	
Reporting group title	XXB750 30 mg
Reporting group description: XXB750 30 mg	
Reporting group title	Placebo
Reporting group description: Placebo	
Reporting group title	XXB750 120 mg
Reporting group description: XXB750 120 mg	
Reporting group title	XXB750 240 mg
Reporting group description: XXB750 240 mg	
Reporting group title	XXB750 60 mg
Reporting group description: XXB750 60 mg	

Serious adverse events	XXB750 30 mg	Placebo	XXB750 120 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 32 (6.25%)	1 / 42 (2.38%)	1 / 37 (2.70%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma cell myeloma			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Coronary artery disease			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Exertional rhabdomyolysis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Device related infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis acute			

subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	XXB750 240 mg	XXB750 60 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 42 (7.14%)	3 / 36 (8.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Plasma cell myeloma			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			

subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Exertional rhabdomyolysis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Device related infection			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			

subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	3 / 42 (7.14%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	XXB750 30 mg	Placebo	XXB750 120 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 32 (59.38%)	27 / 42 (64.29%)	16 / 37 (43.24%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Transitional cell carcinoma			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Glomus tumour			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			

subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Aortic arteriosclerosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Deep vein thrombosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 32 (3.13%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Phlebitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 32 (3.13%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Influenza like illness			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Injection site pain			

subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Sputum discoloured			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Epistaxis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			

subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 32 (3.13%)	1 / 42 (2.38%)	3 / 37 (8.11%)
occurrences (all)	1	1	3
Bronchopneumopathy			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Investigations			
Heart sounds abnormal			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 32 (0.00%)	3 / 42 (7.14%)	0 / 37 (0.00%)
occurrences (all)	0	3	0
Blood creatinine increased			
subjects affected / exposed	2 / 32 (6.25%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
Blood iron abnormal			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			

subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram PR prolongation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST-T segment elevation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram abnormal			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Glucose urine present			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Haematocrit increased			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Haemoglobin increased			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Heart rate abnormal			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0

Prothrombin time prolonged			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Muscle strain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Burns first degree			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Joint injury			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vaccination complication			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	2 / 32 (6.25%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Palpitations			
subjects affected / exposed	1 / 32 (3.13%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Cardiac failure			

subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Diastolic dysfunction			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Left ventricular hypertrophy			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Hypotonia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	2 / 32 (6.25%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Dizziness			
subjects affected / exposed	3 / 32 (9.38%)	2 / 42 (4.76%)	1 / 37 (2.70%)
occurrences (all)	3	2	0
Vertebral artery occlusion			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0

Syncope			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cervical radiculopathy			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 32 (3.13%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
Eye disorders			
Eyelid oedema			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0

Diarrhoea			
subjects affected / exposed	0 / 32 (0.00%)	3 / 42 (7.14%)	0 / 37 (0.00%)
occurrences (all)	0	4	0
Hepatobiliary disorders			
Liver disorder			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Solar urticaria			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Skin swelling			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Albuminuria			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Azotaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Urinary bladder haemorrhage			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Renal failure			

subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Renal cyst			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	2 / 37 (5.41%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Spinal osteoarthritis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	2 / 32 (6.25%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
Neck pain			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Myopathy			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Arthralgia			

subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Infections and infestations			
Injection site cellulitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
COVID-19			
subjects affected / exposed	1 / 32 (3.13%)	4 / 42 (9.52%)	0 / 37 (0.00%)
occurrences (all)	1	4	0
Carbuncle			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Infected bite			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0

Influenza			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	1 / 32 (3.13%)	4 / 42 (9.52%)	4 / 37 (10.81%)
occurrences (all)	1	2	4
Wound infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 32 (3.13%)	2 / 42 (4.76%)	1 / 37 (2.70%)
occurrences (all)	1	2	1
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Gout			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hyperlipidaemia			
subjects affected / exposed	1 / 32 (3.13%)	2 / 42 (4.76%)	1 / 37 (2.70%)
occurrences (all)	1	1	0
Hyperphosphataemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	3 / 37 (8.11%)
occurrences (all)	0	1	1
Vitamin D deficiency			
subjects affected / exposed	0 / 32 (0.00%)	1 / 42 (2.38%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 32 (0.00%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Impaired fasting glucose			

subjects affected / exposed	1 / 32 (3.13%)	0 / 42 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	XXB750 240 mg	XXB750 60 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 42 (42.86%)	18 / 36 (50.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Transitional cell carcinoma			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Glomus tumour			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Basal cell carcinoma			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Uterine leiomyoma			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Aortic arteriosclerosis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Deep vein thrombosis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Hypertension			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	2	
Phlebitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Orthostatic hypotension			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Hypotension			

subjects affected / exposed	1 / 42 (2.38%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Influenza like illness			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Injection site pain			
subjects affected / exposed	1 / 42 (2.38%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Injection site pruritus			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Malaise			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	1 / 42 (2.38%)	3 / 36 (8.33%)	
occurrences (all)	1	4	
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	0	
Benign prostatic hyperplasia			

subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Erectile dysfunction			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Sputum discoloured			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Dyspnoea			
subjects affected / exposed	1 / 42 (2.38%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Cough			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Bronchopneumopathy			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Investigations			

Heart sounds abnormal				
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
Amylase increased				
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)		
occurrences (all)	0	1		
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
Blood creatinine increased				
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)		
occurrences (all)	1	0		
Blood iron abnormal				
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)		
occurrences (all)	1	0		
Blood pressure increased				
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
Electrocardiogram PR prolongation				
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)		
occurrences (all)	0	1		
Electrocardiogram ST-T segment elevation				
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)		
occurrences (all)	0	1		
Electrocardiogram abnormal				
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
Glucose urine present				
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)		
occurrences (all)	0	0		
Haematocrit increased				
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)		
occurrences (all)	0	0		
Haemoglobin increased				

subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Heart rate abnormal			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Liver function test increased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Protein urine present			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Prothrombin time prolonged			
subjects affected / exposed	2 / 42 (4.76%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Transaminases increased			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Muscle strain			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Ankle fracture			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Burns first degree			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Joint dislocation			

subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Joint injury			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Vaccination complication			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Atrial fibrillation			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Cardiac failure			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Diastolic dysfunction			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Left ventricular hypertrophy			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Myocardial ischaemia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Bradycardia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Sinus bradycardia			
subjects affected / exposed	1 / 42 (2.38%)	1 / 36 (2.78%)	
occurrences (all)	0	1	

Supraventricular extrasystoles			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Hypotonia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hypoaesthesia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Dizziness			
subjects affected / exposed	2 / 42 (4.76%)	2 / 36 (5.56%)	
occurrences (all)	2	2	
Vertebral artery occlusion			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Sciatica			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Paraesthesia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Cervical radiculopathy			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Iron deficiency anaemia			

subjects affected / exposed occurrences (all)	0 / 42 (0.00%) 0	1 / 36 (2.78%) 1	
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	 1 / 42 (2.38%) 1	 0 / 36 (0.00%) 0	
Eye disorders Eyelid oedema subjects affected / exposed occurrences (all)	 0 / 42 (0.00%) 0	 1 / 36 (2.78%) 1	
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Toothache subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	 1 / 42 (2.38%) 1 0 / 42 (0.00%) 0 0 / 42 (0.00%) 0 0 / 42 (0.00%) 0	 1 / 36 (2.78%) 1 0 / 36 (0.00%) 0 0 / 36 (0.00%) 0 0 / 36 (0.00%) 0	
Hepatobiliary disorders Liver disorder subjects affected / exposed occurrences (all)	 1 / 42 (2.38%) 1	 0 / 36 (0.00%) 0	
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all) Dermatitis contact subjects affected / exposed occurrences (all) Solar urticaria subjects affected / exposed occurrences (all)	 0 / 42 (0.00%) 0 0 / 42 (0.00%) 0 0 / 42 (0.00%) 0	 1 / 36 (2.78%) 1 0 / 36 (0.00%) 0 0 / 36 (0.00%) 0	

Skin swelling			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Rash			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Miliaria			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Albuminuria			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Azotaemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Renal failure			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Renal cyst			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Proteinuria			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	0	
Nocturia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			

Spinal osteoarthritis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	1 / 42 (2.38%)	1 / 36 (2.78%)	
occurrences (all)	1	1	
Neck pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Myopathy			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Joint swelling			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Arthralgia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Injection site cellulitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Acute sinusitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
COVID-19			

subjects affected / exposed	3 / 42 (7.14%)	0 / 36 (0.00%)	
occurrences (all)	2	0	
Carbuncle			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Cellulitis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	1 / 42 (2.38%)	1 / 36 (2.78%)	
occurrences (all)	1	0	
Erysipelas			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Infected bite			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Laryngitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Oral candidiasis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Pneumonia aspiration			

subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Tooth infection			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Urinary tract infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Wound infection			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Gout			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	1	
Hypercholesterolaemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Hyperglycaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 42 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	1	
Hyperlipidaemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	

Hyperphosphataemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 36 (0.00%)	
occurrences (all)	1	0	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Hyperuricaemia			
subjects affected / exposed	2 / 42 (4.76%)	1 / 36 (2.78%)	
occurrences (all)	2	1	
Hypokalaemia			
subjects affected / exposed	0 / 42 (0.00%)	2 / 36 (5.56%)	
occurrences (all)	0	1	
Vitamin D deficiency			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 42 (0.00%)	1 / 36 (2.78%)	
occurrences (all)	0	0	
Impaired fasting glucose			
subjects affected / exposed	0 / 42 (0.00%)	0 / 36 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 June 2023	This amendment was generated to update some of the inclusion/exclusion criteria.
05 March 2024	This amendment was generated: • To clarify the treatment unblinding during primary endpoint and safety analysis when all participants have completed week 12 or discontinued from the study. • Stage 2 of the study was eliminated as the primary purpose of this study was to evaluate the dose response of different doses of XXB750 vs. placebo. • Updated model averaging method in using bootstrapping samples.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported