



Clinical trial results:

A single-arm, multicenter, nilotinib treatment-free remission study in patients with BCR- ABL1 positive Chronic Myelogenous Leukemia in chronic phase who have achieved durable minimal residual disease (MRD) status on first-line nilotinib treatment.

Summary

EudraCT number	2012-004092-40
Trial protocol	SE AT IT GB ES BE IE PL DK NL GR HU FR BG
Global end of trial date	23 January 2025

Results information

Result version number	v1 (current)
This version publication date	07 February 2026
First version publication date	07 February 2026

Trial information

Trial identification

Sponsor protocol code	CAMN107I2201
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01784068
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharmaceuticals
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharmaceuticals, 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	23 January 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to determine the percentage of patients who were in MMR at 48 weeks after starting the TFR phase.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.nov> for complete trial results.

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	19 March 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Hungary: 10
Country: Number of subjects enrolled	Ireland: 7
Country: Number of subjects enrolled	Italy: 21
Country: Number of subjects enrolled	Japan: 18
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Poland: 9
Country: Number of subjects enrolled	Spain: 29
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	United States: 14
Country: Number of subjects enrolled	Argentina: 1
Country: Number of subjects enrolled	Austria: 5
Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Bulgaria: 3
Country: Number of subjects enrolled	Colombia: 2
Country: Number of subjects enrolled	Denmark: 5
Country: Number of subjects enrolled	France: 22
Country: Number of subjects enrolled	Germany: 45

Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Greece: 5
Worldwide total number of subjects	215
EEA total number of subjects	177

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	171
From 65 to 84 years	43
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Recruitment for the study comprised a total of 215 participants, who were enrolled at 132 clinical sites distributed across 19 different countries..

Pre-assignment

Screening details:

Informed consent was obtained from each participant in writing before screening and before any study specific procedure was performed.

Period 1

Period 1 title	NTCS Phase
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Nilotinib Treatment and Treatment-Free Remission Cohort
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Arm description:

Participants who received nilotinib during the consolidation phase and, if eligible, entered the treatment-free remission phase following nilotinib discontinuation.

Arm type	Experimental
Investigational medicinal product name	Nilotinib
Investigational medicinal product code	AMN107
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Clinical packs were labeled as AMN107 and supplied as 150 mg and 200 mg hard gelatin capsules in bottles. The planned dose of nilotinib was 300 mg b.i.d.

Number of subjects in period 1	Nilotinib Treatment and Treatment-Free Remission Cohort
Started	215
Completed	203
Not completed	12
Adverse event, serious fatal	2
Physician decision	2
Adverse event, non-fatal	5
Patient/guardian decision	3

Period 2

Period 2 title	TFS Phase
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Nilotinib Treatment and Treatment-Free Remission Cohort
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Arm description:

Participants who received nilotinib during the consolidation phase and, if eligible, entered the treatment-free remission phase following nilotinib discontinuation.

Arm type	Experimental
Investigational medicinal product name	Nilotinib
Investigational medicinal product code	AMN107
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Clinical packs were labeled as AMN107 and supplied as 150 mg and 200 mg hard gelatin capsules in bottles. The planned dose of nilotinib was 300 mg b.i.d.

Number of subjects in period 2^[1]	Nilotinib Treatment and Treatment-Free Remission Cohort
Started	190
Completed	65
Not completed	125
Adverse event, serious fatal	2
Physician decision	4
Patient/guardian decision	18
Lost to follow-up	3
Lack of efficacy	98

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: Participants who received nilotinib during the consolidation phase and, if eligible, entered the treatment-free remission phase following nilotinib discontinuation

Baseline characteristics

Reporting groups

Reporting group title	Nilotinib Treatment and Treatment-Free Remission Cohort
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Reporting group description:

Participants who received nilotinib during the consolidation phase and, if eligible, entered the treatment-free remission phase following nilotinib discontinuation.

Reporting group values	Nilotinib Treatment and Treatment-Free Remission Cohort	Total	
Number of subjects	215	215	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	171	171	
From 65-84 years	43	43	
85 years and over	1	1	
Age Continuous Units: years			
median	54.0		
full range (min-max)	21 to 86	-	
Sex: Female, Male Units: participants			
Female	102	102	
Male	113	113	
Race/Ethnicity, Customized Units: Subjects			
Caucasian	189	189	
Asian	20	20	
Unknown	3	3	
Native American	1	1	
Other	2	2	

End points

End points reporting groups

Reporting group title	Nilotinib Treatment and Treatment-Free Remission Cohort
Reporting group description: Participants who received nilotinib during the consolidation phase and, if eligible, entered the treatment-free remission phase following nilotinib discontinuation.	
Reporting group title	Nilotinib Treatment and Treatment-Free Remission Cohort
Reporting group description: Participants who received nilotinib during the consolidation phase and, if eligible, entered the treatment-free remission phase following nilotinib discontinuation.	
Subject analysis set title	NTCS phase
Subject analysis set type	Full analysis
Subject analysis set description: Participants who had received at least 2 years of first-line nilotinib treatment and achieved a deep molecular response (MR4.5) entered the nilotinib treatment consolidation (NTCS) phase. During this phase, participants received nilotinib 300 mg twice daily for 52 weeks.	
Subject analysis set title	TFR phase
Subject analysis set type	Full analysis
Subject analysis set description: Participants who completed the nilotinib treatment consolidation (NTCS) phase and maintained major molecular response entered the treatment-free remission (TFR) phase. During the TFR phase, nilotinib treatment was discontinued and participants were monitored regularly for molecular response.	
Subject analysis set title	TFR phase
Subject analysis set type	Full analysis
Subject analysis set description: Participants who completed the nilotinib treatment consolidation (NTCS) phase and maintained major molecular response entered the treatment-free remission (TFR) phase. During the TFR phase, nilotinib treatment was discontinued and participants were monitored regularly for molecular response.	
Subject analysis set title	TFR phase
Subject analysis set type	Full analysis
Subject analysis set description: Participants who completed the nilotinib treatment consolidation (NTCS) phase and maintained major molecular response entered the treatment-free remission (TFR) phase. During the TFR phase, nilotinib treatment was discontinued and participants were monitored regularly for molecular response.	
Subject analysis set title	TFR phase
Subject analysis set type	Full analysis
Subject analysis set description: Participants who completed the nilotinib treatment consolidation (NTCS) phase and maintained major molecular response entered the treatment-free remission (TFR) phase. During the TFR phase, nilotinib treatment was discontinued and participants were monitored regularly for molecular response.	
Subject analysis set title	NTRI phase
Subject analysis set type	Safety analysis
Subject analysis set description: Participants who experienced loss of major molecular response during the treatment-free remission (TFR) phase entered the nilotinib treatment re-initiation (NTRI) phase. During this phase, nilotinib treatment was re-initiated at a dose of 300 mg twice daily.	
Subject analysis set title	NTRI phase
Subject analysis set type	Safety analysis
Subject analysis set description: Participants who experienced loss of major molecular response during the treatment-free remission (TFR) phase entered the nilotinib treatment re-initiation (NTRI) phase. During this phase, nilotinib treatment was re-initiated at a dose of 300 mg twice daily.	
Subject analysis set title	NTRI phase
Subject analysis set type	Safety analysis
Subject analysis set description: Participants who experienced loss of major molecular response during the treatment-free remission (TFR) phase entered the nilotinib treatment re-initiation (NTRI) phase. During this phase, nilotinib treatment was re-initiated at a dose of 300 mg twice daily.	
Subject analysis set title	NTRI phase
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who experienced loss of major molecular response during the treatment-free remission (TFR) phase entered the nilotinib treatment re-initiation (NTRI) phase. During this phase, nilotinib treatment was re-initiated at a dose of 300 mg twice daily.

Subject analysis set title	TFR phase
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who completed the nilotinib treatment consolidation (NTCS) phase and maintained major molecular response entered the treatment-free remission (TFR) phase. During the TFR phase, nilotinib treatment was discontinued and participants were monitored regularly for molecular response.

Primary: Percentage of participants in Major Molecular Response at 48 weeks after start of Treatment-Free Remission (TFR) phase

End point title	Percentage of participants in Major Molecular Response at 48 weeks after start of Treatment-Free Remission (TFR) phase ^[1]
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End point description:

The primary endpoint was the percentage of participants in major molecular response (MMR) at 48 weeks after initiation of the treatment-free remission (TFR) phase. Participants who required re-initiation of treatment were considered as non-responders.

End point type	Primary
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End point timeframe:

48 weeks in TFR

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: No statistical analysis was planned for this primary outcome

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	98			
Units: percentage of participants				
number (confidence interval 95%)	51.6 (44.2 to 58.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in MR4.5 (BCR-ABL ≤ 0.0032% IS) at 48 weeks after start of TFR phase

End point title	Percentage of participants in MR4.5 (BCR-ABL ≤ 0.0032% IS) at 48 weeks after start of TFR phase
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End point description:

The outcome measure was the percentage of participants in molecular response 4.5 (MR4.5) at 48 weeks after initiation of the treatment-free remission (TFR) phase. Participants who required reinitiation of treatment were considered non-responders. MR4.5 corresponds to a BCR-ABL transcript level ≤0.0032% on the International Scale (IS), representing a deep molecular response.

End point type	Secondary
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End point timeframe:

48 weeks in TFR

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	90			
Units: percentage of participants				
number (confidence interval 95%)	47.4 (40.1 to 54.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants in Major Molecular Response (MMR) at Multiple Time Points After Start of the Treatment-Free Remission (TFR) Phase

End point title	Percentage of Participants in Major Molecular Response (MMR) at Multiple Time Points After Start of the Treatment-Free Remission (TFR) Phase
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End point description:

This outcome measure was the percentage of participants in major molecular response (MMR) assessed at multiple timepoints after initiation of the treatment-free remission (TFR) phase. Participants who required reinitiation of treatment at any time prior to the respective assessment were considered non-responders.

End point type	Secondary
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End point timeframe:

Weeks 96, 144, 192, and 264, and End of Years 6, 7, 8, 9, and 10

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	190			
Units: percentage of participants				
number (confidence interval 95%)				
Week 96 response	48.9 (41.6 to 56.3)			
Week 144 response	46.8 (39.6 to 54.2)			
Week 192 response	44.7 (37.5 to 52.1)			
Week 264 response	41.6 (34.5 to 48.9)			
Week 312 (Year 6) response	38.4 (31.5 to 45.7)			
Week 360 (Year 7) response	37.4 (30.5 to 44.7)			
Week 408 (year 8) response	35.3 (28.5 to 42.5)			
Week 468 (year 9) response	34.2 (27.5 to 41.4)			

Week 528 (year 10) response	26.8 (20.7 to 33.7)			
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Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants in Molecular Response 4.5 (MR4.5) at Multiple Time Points After Start of the Treatment-Free Remission (TFR) Phase

End point title	Percentage of Participants in Molecular Response 4.5 (MR4.5) at Multiple Time Points After Start of the Treatment-Free Remission (TFR) Phase
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End point description:

This secondary outcome measure was the percentage of participants in molecular response 4.5 (MR4.5) assessed at multiple timepoints after initiation of the treatment-free remission (TFR) phase. Participants who required reinitiation of treatment at any time prior to the respective assessment were considered non-responders. MR4.5 corresponds to a BCR-ABL transcript level $\leq 0.0032\%$ on the International Scale (IS).

End point type	Secondary
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End point timeframe:

Weeks 96, 144, 192, and 264, and End of Years 6, 7, 8, 9, and 10

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	190			
Units: percentage of participants				
number (confidence interval 95%)				
Week 96 response	46.3 (39.1 to 53.7)			
Week 144 response	45.8 (38.6 to 53.2)			
Week 192 response	43.2 (36.0 to 50.5)			
Week 264 response	40.0 (33.0 to 47.3)			
Week 312 (Year 6) response	37.9 (31.0 to 45.2)			
Week 360 (Year 7) response	36.3 (29.5 to 43.6)			
Week 408 (year 8) response	35.3 (28.5 to 42.5)			
Week 468 (year 9) response	33.7 (27.0 to 40.9)			
Week 528 (year 10) response	25.3 (19.3 to 32.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants in Major Molecular Response (MMR) at Multiple Time Points After Start of the Treatment-Free Remission (TFR) Phase

End point title	Number of Participants in Major Molecular Response (MMR) at Multiple Time Points After Start of the Treatment-Free Remission (TFR) Phase
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End point description:

This outcome measure was the number of participants in major molecular response (MMR) assessed at multiple timepoints after initiation of the treatment-free remission (TFR) phase of nilotinib. At each assessment time point, participants with available MMR data were counted. Participants who reinitiated nilotinib treatment for less than 12 weeks prior to the respective assessment time point were excluded from the analysis at that time point.

End point type	Secondary
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End point timeframe:

Weeks 48, 96, 144, 192, and 264, and End of Years 6, 7, 8, 9, and 10

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	190			
Units: participants				
Week 48 response	98			
Week 96 response	93			
Week 144 response	89			
Week 192 response	85			
Week 264 response	79			
Week 312 (Year 6) response	73			
Week 360 (Year 7) response	71			
Week 408 (year 8) response	67			
Week 468 (year 9) response	65			
Week 528 (year 10) response	51			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants in Molecular Response 4.5 (MR4.5) at Multiple Time Points After Start of the Treatment-Free Remission (TFR) Phase

End point title	Number of Participants in Molecular Response 4.5 (MR4.5) at Multiple Time Points After Start of the Treatment-Free Remission (TFR) Phase
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End point description:

This outcome measure was the number of participants in molecular response 4.5 (MR4.5) assessed at multiple timepoints after initiation of the treatment-free remission (TFR) phase of nilotinib. At each assessment time point, participants with available MR4.5 data were counted. Participants who reinitiated nilotinib treatment for less than 12 weeks prior to the respective assessment time point were excluded from the analysis at that time point. MR4.5 corresponds to a BCR-ABL transcript level $\leq 0.0032\%$ on the International Scale (IS).

End point type	Secondary
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End point timeframe:

Weeks 48, 96, 144, 192, and 264, and End of Years 6, 7, 8, 9, and 10

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	190			
Units: Participants				
Week 48 response	90			
Week 96 response	88			
Week 144 response	87			
Week 192 response	82			
Week 264 response	76			
Week 312 (Year 6) response	72			
Week 360 (Year 7) response	69			
Week 408 (year 8) response	67			
Week 468 (year 9) response	64			
Week 528 (year 10) response	48			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved Major Molecular Response (MMR) Within 12 Weeks of Reinitiation of Nilotinib Treatment

End point title	Percentage of Participants Who Achieved Major Molecular Response (MMR) Within 12 Weeks of Reinitiation of Nilotinib Treatment
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End point description:

Proportion of patients who achieved MMR within 12 weeks of re-initiation of treatment with nilotinib defined as the number of patients who were in MMR at least at 1 assessment within 12 weeks after re-start of nilotinib treatment divided by the number of patients who were re-initiated for at least 12 weeks.

End point type	Secondary
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End point timeframe:

12 weeks after reinitiation of nilotinib treatment

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	87			
Units: percentage of participants				
number (confidence interval 95%)	95.4 (88.6 to 98.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Stable Major Molecular Response (MMR) at Multiple Time Points After First Achievement of MMR During Nilotinib Re-Initiation

End point title	Percentage of Participants With Stable Major Molecular Response (MMR) at Multiple Time Points After First Achievement of MMR During Nilotinib Re-Initiation
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End point description:

The proportion of patients who were in stable MMR after achieving a response in the NTRI phase at multiple timepoints was calculated by dividing the number of participants achieving MMR any time during the NTRI phase and having the same response at those timepoints after the first achievement of MMR, irrespective of whether there was loss of MMR in between, by the number of patients who achieved MMR at any time during the NTRI phase.

End point type	Secondary
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End point timeframe:

Weeks 48, 96, 144, 192, 240, 288, 336, 384, and 432 after first achievement of MMR during the nilotinib re-initiation phase

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	89			
Units: percentage of participants				
number (confidence interval 95%)				
Stable MMR for 48 weeks	84.3 (75.0 to 91.1)			
Stable MMR for 96 weeks	78.7 (68.7 to 86.6)			
Stable MMR for 144 weeks	68.5 (57.8 to 78.0)			
Stable MMR for 192 weeks	60.7 (49.7 to 70.9)			
Stable MMR for 240 weeks	48.3 (37.6 to 59.2)			
Stable MMR for 288 weeks	42.7 (32.3 to 53.6)			
Stable MMR for 336 weeks	38.2 (28.1 to 49.1)			
Stable MMR for 384 weeks	34.8 (25.0 to 45.7)			
Stable MMR for 432 weeks	30.3 (21.0 to 41.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Stable Molecular Response 4.5 (MR4.5) at Multiple Time Points After First Achievement During Nilotinib Re-Initiation

End point title	Percentage of Participants With Stable Molecular Response 4.5 (MR4.5) at Multiple Time Points After First Achievement During Nilotinib Re-Initiation
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End point description:

The proportion of patients who were in stable MR4.5 after achieving a response in the NTRI phase at multiple timepoints was calculated by dividing the number of participants achieving MR4.5 any time during the NTRI phase and having the same response at those timepoints after the first achievement of MR4.5, irrespective of whether there was loss of MR4.5 in between, by the number of patients who achieved MR4.5 at any time during the NTRI phase.

End point type	Secondary
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End point timeframe:

Weeks 48, 96, 144, 192, 240, 288, 336, 384, and 432 after first achievement of MR4.5 during the nilotinib re-initiation phase

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	84			
Units: percentage of participants				
number (confidence interval 95%)				
Stable MR4.5 for 48 weeks	86.9 (77.8 to 93.3)			
Stable MR4.5 for 96 weeks	76.2 (65.7 to 84.8)			
Stable MR4.5 for 144 weeks	71.4 (60.5 to 80.8)			
Stable MR4.5 for 192 weeks	63.1 (51.9 to 73.4)			
Stable MR4.5 for 240 weeks	48.8 (37.7 to 60.0)			
Stable MR4.5 for 288 weeks	42.9 (32.1 to 54.1)			
Stable MR4.5 for 336 weeks	39.3 (28.8 to 50.5)			
Stable MR4.5 for 384 weeks	35.7 (25.6 to 46.9)			
Stable MR4.5 for 432 weeks	31.0 (21.3 to 42.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Re-Initiated Nilotinib Treatment Required to Regain Major Molecular Response (MMR) After Loss of MMR

End point title	Duration of Re-Initiated Nilotinib Treatment Required to Regain Major Molecular Response (MMR) After Loss of MMR
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End point description:

This outcome measure was defined as the time from the date of reinitiation of nilotinib treatment following loss of major molecular response (MMR) to the date of first documented achievement of MMR. Participants who did not regain MMR after reinitiation of treatment on or before the data cut-off date were censored at the date of their last available BCR-ABN PCR assessment.

End point type	Secondary
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End point timeframe:

Every 4 weeks up to Week 24, and every 12 weeks thereafter, up to Week 528 after the last participant entered the treatment-free remission (TFR) phase

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	91			
Units: Weeks				
median (confidence interval 95%)	7.0 (5.0 to 8.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Re-Initiated Nilotinib Treatment Required to Regain Molecular Response 4.5 (MR4.5) After Loss of MMR

End point title	Duration of Re-Initiated Nilotinib Treatment Required to Regain Molecular Response 4.5 (MR4.5) After Loss of MMR
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End point description:

This outcome measure was defined as the time from the date of reinitiation of nilotinib treatment following loss of major molecular response (MMR) to the date of first documented achievement of molecular response 4.5 (MR4.5). Participants who did not regain MR4.5 after reinitiation of treatment on or before the data cut-off date were censored at the date of their last available BCR-ABN PCR assessment. MR4.5 corresponds to a BCR-ABN transcript level $\leq 0.0032\%$ on the International Scale (IS).

End point type	Secondary
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End point timeframe:

Every 4 weeks up to Week 24, and every 12 weeks thereafter, up to Week 528 after the last participant entered the treatment-free remission (TFR) phase

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	91			
Units: Weeks				
median (confidence interval 95%)	12.9 (12.1 to 15.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment-Free Survival (TFS) After Start of the Treatment-Free Remission (TFR) Phase

End point title	Treatment-Free Survival (TFS) After Start of the Treatment-Free Remission (TFR) Phase
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End point description:

Treatment-free survival (TFS) was defined as the time from the start of the treatment-free remission (TFR) phase to the earliest occurrence of loss of major molecular response (MMR), reinitiation of treatment for any reason, progression to accelerated phase (AP) or blast crisis (BC), or death due to any cause. Participants without an event on or before the data cut-off date were censored at the date of their last available disease assessment (polymerase chain reaction, cytogenetic, hematologic, or extramedullary assessment).

End point type	Secondary
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End point timeframe:

From start of the treatment-free remission (TFR) phase up to Week 528

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	190			
Units: Weeks				
median (confidence interval 95%)	120.1 (36.9 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) After Start of the Treatment-Free Remission (TFR) Phase

End point title	Progression-Free Survival (PFS) After Start of the Treatment-Free Remission (TFR) Phase
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End point description:

Progression-free survival (PFS) was defined as the time from the start of the treatment-free remission (TFR) phase to the earliest occurrence of disease progression to accelerated phase (AP) or blast crisis (BC), or death due to any cause. Participants without an event on or before the data cut-off date were censored at the date of their last available disease assessment (cytogenetic, hematologic, or extramedullary assessment) or last contact for participants in follow-up.

End point type	Secondary
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End point timeframe:

From start of the treatment-free remission (TFR) phase up to Week 528

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	190			
Units: Weeks				
median (confidence interval 95%)	999 (999 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) After Start of the Treatment-Free Remission (TFR) Phase

End point title	Overall Survival (OS) After Start of the Treatment-Free Remission (TFR) Phase
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End point description:

Overall survival (OS) was defined as the time from the start of the treatment-free remission (TFR) phase to death due to any cause. Participants who were alive on or before the data cut-off date were censored at the date of their last assessment or last known alive date for participants in follow-up.

End point type	Secondary
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End point timeframe:

From start of the treatment-free remission (TFR) phase up to Week 528

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	190			
Units: Weeks				
median (confidence interval 95%)	999 (999 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants With BCR-ABL1 Mutations Associated With Resistance to Nilotinib After Loss of Major Molecular Response

End point title	Percentage of participants With BCR-ABL1 Mutations Associated With Resistance to Nilotinib After Loss of Major Molecular Response
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End point description:

This outcome measure was the percentage of participants who developed BCR-ABL1 mutations associated with resistance to nilotinib following loss of major molecular response (MMR) after suspension of nilotinib treatment. Mutations assessed included, but were not limited to, T315I, E255K, Y253H, F359V, F359C, and F359I. The endpoint was calculated as the number of participants with at least one detected BCR-ABL1 mutation divided by the number of participants who experienced loss of MMR after nilotinib suspension.

End point type	Secondary
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End point timeframe:

From loss of major molecular response after nilotinib suspension through up to 528 weeks of study participation

End point values	TFR phase			
Subject group type	Subject analysis set			
Number of subjects analysed	76			
Units: percentage of participants	1			

Statistical analyses

No statistical analyses for this end point

Secondary: BCR-ABL ratio (%) over time in nilotinib treatment re-initiation phase (NTRI)

End point title	BCR-ABL ratio (%) over time in nilotinib treatment re-initiation phase (NTRI)
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End point description:

This outcome measure evaluated the kinetics of BCR-ABL transcript levels over time following reinitiation of nilotinib therapy. BCR-ABL transcript levels were assessed at baseline (time of reinitiation), every 4 weeks up to Week 24, and every 12 weeks thereafter, up to Week 528 after the last participant entered the treatment-free remission (TFR) phase. Summary statistics at each scheduled assessment time point included the number of participants assessed, mean BCR-ABL transcript level, and standard deviation.

End point type	Secondary
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End point timeframe:

Baseline; every 4 weeks up to Week 24; and every 12 weeks thereafter, up to Week 528 after the last participant entered the treatment-free remission (TFR) phase

End point values	NTRI phase			
Subject group type	Subject analysis set			
Number of subjects analysed	91			
Units: Percent				
arithmetic mean (standard deviation)				
Baseline	0.22697 (± 0.194306)			
Week 4	0.43848 (± 1.302378)			
Week 8	0.14038 (± 0.527741)			
Week 12	0.03205 (± 0.172524)			
Week 16	0.01044 (± 0.055724)			
Week 20	0.00476 (± 0.027446)			
Week 24	0.00291 (± 0.011041)			

Week 36	0.00209 (\pm 0.010182)			
Week 48	0.00149 (\pm 0.007022)			
Week 60	0.00120 (\pm 0.006373)			
Week 72	0.00098 (\pm 0.003366)			
Week 84	0.00120 (\pm 0.006416)			
Week 96	0.00169 (\pm 0.010148)			
Week 108	0.00492 (\pm 0.032543)			
Week 120	0.00073 (\pm 0.002945)			
Week 132	0.00055 (\pm 0.002217)			
Week 144	0.00068 (\pm 0.002429)			
Week 156	0.00074 (\pm 0.003559)			
Week 168	0.00071 (\pm 0.003267)			
Week 180	0.00047 (\pm 0.001156)			
Week 192	0.00262 (\pm 0.016285)			
Week 204	0.01753 (\pm 0.126293)			
Week 216	0.00683 (\pm 0.048460)			
Week 228	0.00427 (\pm 0.029012)			
Week 240	0.00315 (\pm 0.016585)			
Week 252	0.00660 (\pm 0.029570)			
Week 264	0.01436 (\pm 0.061134)			
Week 276	0.01784 (\pm 0.081702)			
Week 288	0.01616 (\pm 0.098699)			
Week 300	0.01865 (\pm 0.113939)			
Week 312	0.02516 (\pm 0.124114)			
Week 324	0.01939 (\pm 0.113715)			
Week 336	0.01348 (\pm 0.078374)			
Week 348	0.00801 (\pm 0.045810)			
Week 360	0.01015 (\pm 0.057496)			
Week 372	0.00509 (\pm 0.028312)			
Week 384	0.00206 (\pm 0.010247)			
Week 396	0.00137 (\pm 0.006892)			

Week 408	0.00158 (± 0.007350)			
Week 420	0.00171 (± 0.008446)			
Week 432	0.00102 (± 0.004642)			
Week 444	0.00057 (± 0.002430)			
Week 456	0.00084 (± 0.002877)			
Week 468	0.00083 (± 0.003204)			
Week 480	0.03371 (± 0.156501)			
Week 492	0.00062 (± 0.002046)			
Week 504	0.00044 (± 0.001246)			
Week 516	0.00073 (± 0.001920)			
Week 528	0.00000 (± 0.00000)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with treatment-emergent adverse events during the entire study

End point title	Percentage of participants with treatment-emergent adverse events during the entire study
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End point description:

This outcome measure summarized the overall occurrence of adverse events related to nilotinib during the study. A study drug-related adverse event was defined as any adverse event assessed by the investigator as related to nilotinib and reported during the nilotinib treatment consolidation (NTCS) phase, the treatment-free remission (TFR) phase, or the nilotinib treatment re-initiation (NTRI) phase.

End point type	Secondary
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End point timeframe:

From first dose of nilotinib through up to 528 weeks of study participation, including the NTCS, TFR, and NTRI phases

End point values	NTCS phase	TFR phase	NTRI phase	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	215	190	91	
Units: participants	83	40	70	

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from first dose nilotinib through up to 528 weeks (approximately 10 years) of study participation.

Adverse event reporting additional description:

Any sign or symptom that occurs from first dose nilotinib through up to 528 weeks (approximately 10 years) of study participation.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	Nilotinib treatment consolidation (NTCS) phase
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Reporting group description:

During the first 52 weeks of the consolidation phase, all patients were treated with the planned dose of 300 mg nilotinib b.i.d. (or at a reduced dose level of 400 mg once daily if patients did not tolerate the planned dose). The treatment continued until the patient experienced unacceptable toxicity, disease progression, death, lost to follow-up and/or treatment was discontinued at the discretion of the Investigator or withdrawal of consent. In order for patients to be eligible for the TFR phase, they had to fulfill the protocol specific definition of durable MRD.

Reporting group title	Nilotinib treatment-free remission (TFR) phase
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Reporting group description:

Patients who fulfilled the protocol specific definition of durable MRD at the end of the NTCS phase were to suspend nilotinib therapy on the day they entered this phase.

Reporting group title	Nilotinib treatment re-initiation (NTRI) phase
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Reporting group description:

If a patient had a loss of MMR (BCR::ABL1 > 0.1% IS) in the TFR phase, the patient restarted nilotinib treatment. Patients were on nilotinib treatment for up to 528 weeks after the last patient entered the nilotinib TFR phase.

Reporting group title	Nilotinib treatment continuation (NTCT) phase
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Reporting group description:

If a patient was ineligible to start the TFR phase, he/she continued the nilotinib treatment in the continuation phase (52 weeks).

Reporting group title	Nilotinib treatment-free remission-2 (TFR-2) phase
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Reporting group description:

Patients who fulfilled the protocol specific definition of durable MRD after the continuation phase (NTCT) were to suspend nilotinib therapy on the day they entered this phase. Duration of the TFR-2 phase and the BCR::ABL1 transcript level monitoring schedule was the same as that for the TFR phase. During the TFR-2 phase, the same rules in case of loss of MR4.0 or of MMR were applied as during the TFR phase.

Reporting group title	Nilotinib treatment re-initiation-2 (NTRI-2) phase
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Reporting group description:

In the nilotinib TFR-2 phase, loss of MMR required nilotinib treatment re-initiation and patients were to enter NTRI-2 phase. The NTRI-2 phase was conducted in the same manner as the NTRI phase.

Reporting group title	Nilotinib treatment prolonged continuation (NTCT - P) phase
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Reporting group description:

Patients were eligible to enter the TFR-2 phase after the NTCT phase if they fulfilled the protocol-specific definition of durable MRD. Patients who did not qualify to start TFR-2 continued to receive nilotinib treatment in the NTCT-P phase for up to 528 weeks after the last patient entered the nilotinib TFR phase, or until the patient experienced unacceptable toxicity, disease progression, death, loss to follow-up, and/or the treatment was discontinued at the discretion of the Investigator or withdrawal of consent. The patients in the NTCT-P phase were followed for safety and efficacy (PCR data).

Reporting group title	All patients
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Reporting group description:

All the patients enrolled in the study

Serious adverse events	Nilotinib treatment consolidation (NTCS) phase	Nilotinib treatment-free remission (TFR) phase	Nilotinib treatment re-initiation (NTRI) phase
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 215 (9.30%)	34 / 190 (17.89%)	40 / 91 (43.96%)
number of deaths (all causes)	2	2	5
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer in situ			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Hepatobiliary cancer			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant melanoma			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Meningioma			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloma			

subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesothelioma			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Penile squamous cell carcinoma			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Prostate cancer			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Renal neoplasm			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Transitional cell carcinoma			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic stenosis			

subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	2 / 91 (2.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	2 / 215 (0.93%)	2 / 190 (1.05%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	3 / 3	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (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
Peripheral artery stenosis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chest pain			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Vascular stent occlusion			

subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Hypersensitivity			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Cough			

subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (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
Dyspnoea			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Hydrothorax			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Pleural effusion			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Pleurisy			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Pulmonary embolism			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Respiratory failure			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Completed suicide			

subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Femur fracture			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Fracture displacement			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Fractured sacrum			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Incisional hernia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Procedural pain			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Seroma			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (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
Wrist fracture			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Congenital, familial and genetic disorders			
Phimosis			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Vallecular cyst			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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

Acute myocardial infarction			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Angina pectoris			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Atrial fibrillation			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	3 / 91 (3.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiac failure congestive			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Cardiac failure			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Cardiomyopathy			

subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	3 / 91 (3.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery dissection			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Coronary artery occlusion			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (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 stenosis			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Myocardial infarction			
subjects affected / exposed	1 / 215 (0.47%)	1 / 190 (0.53%)	4 / 91 (4.40%)
occurrences causally related to treatment / all	1 / 1	0 / 1	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prinzmetal angina			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid artery dissection			

subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Carotid artery stenosis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (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
Carpal tunnel syndrome			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Headache			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			

subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis relapse			
subjects affected / exposed	1 / 215 (0.47%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	2 / 91 (2.20%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Thalamic infarction			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Retinal degeneration			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Optic atrophy			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iris neovascularisation			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (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
Abdominal pain			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Abdominal pain upper			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Ascites			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Duodenitis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			

subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Haemorrhoids			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Intestinal obstruction			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Inguinal hernia			
subjects affected / exposed	2 / 215 (0.93%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Nausea			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Pancreatitis			
subjects affected / exposed	2 / 215 (0.93%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	2 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			

subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Hepatomegaly			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	2 / 91 (2.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Urinary incontinence			

subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Urethral obstruction			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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			
Back pain			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Chondropathy			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Cervical spinal stenosis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Facet joint syndrome			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	2 / 215 (0.93%)	2 / 190 (1.05%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 215 (0.00%)	3 / 190 (1.58%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Spondylolisthesis			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Infections and infestations			

Bacteraemia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryocystitis			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (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
Gastroenteritis			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Parapharyngeal space infection			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 215 (0.00%)	2 / 190 (1.05%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Rectal abscess			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Postoperative wound infection			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Respiratory tract infection			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (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
Hypokalaemia			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Nilotinib treatment continuation (NTCT) phase	Nilotinib treatment-free remission-2 (TFR-2) phase	Nilotinib treatment re-initiation-2 (NTRI-2) phase
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 13 (7.69%)	1 / 10 (10.00%)	3 / 5 (60.00%)
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)			
Basal cell carcinoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Breast cancer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Breast cancer in situ			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Hepatobiliary cancer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Malignant melanoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Meningioma			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Papilloma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Mesothelioma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Penile squamous cell carcinoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Prostate cancer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Rectal cancer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Renal neoplasm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Transitional cell carcinoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Squamous cell carcinoma			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Haematoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Hypertension			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (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
Peripheral artery stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Chest pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (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

Gait disturbance			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Vascular stent occlusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Generalised oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Prostatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (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
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Hydrothorax			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Pleurisy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Respiratory failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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

Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Femur fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Fracture displacement			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Fractured sacrum			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Hip fracture			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Incisional hernia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Joint dislocation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Procedural pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Seroma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Congenital, familial and genetic disorders			
Phimosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Vallecular cyst			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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			

Acute coronary syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Angina pectoris			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Atrial fibrillation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Atrial flutter			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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 arrest			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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 failure congestive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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 failure			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery dissection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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 occlusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Myocardial infarction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Pericardial effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Prinzmetal angina			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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			
Carotid artery dissection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Carotid artery stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Cerebral infarction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Cervicobrachial syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Dizziness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Headache			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Ischaemic stroke			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Multiple sclerosis relapse			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Myelopathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Syncope			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Thalamic infarction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Eye disorders			
Retinal degeneration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Optic atrophy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Iris neovascularisation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Abdominal pain upper			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Ascites			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Duodenitis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Dysphagia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Gastric ulcer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Haemorrhoids			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Intestinal obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Inguinal hernia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Large intestine polyp			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Pancreatitis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Retroperitoneal haematoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Stomatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Hepatomegaly			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Renal colic			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Renal failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Renal impairment			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Urinary incontinence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Urethral obstruction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Bone pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Chondropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Cervical spinal stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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

Intervertebral disc degeneration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Facet joint syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Osteoarthritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Polymyalgia rheumatica			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Spondylolisthesis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Dacryocystitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Herpes zoster			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Gastroenteritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Parapharyngeal space infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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 aspiration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Rectal abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Postoperative wound infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Hypokalaemia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (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

Serious adverse events	Nilotinib treatment prolonged continuation (NTCT - P) phase	All patients	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	84 / 215 (39.07%)	
number of deaths (all causes)	0	9	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer in situ			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary cancer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant melanoma			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 3 (0.00%)	4 / 215 (1.86%)	
occurrences causally related to treatment / all	0 / 0	5 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Prostatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture displacement			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured sacrum			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Phimosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vallecular cyst			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cardiac failure congestive			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
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 / 3 (0.00%)	4 / 215 (1.86%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery dissection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	6 / 215 (2.79%)	
occurrences causally related to treatment / all	0 / 0	4 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prinzmetal angina			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Carotid artery dissection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple sclerosis relapse			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic infarction			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Retinal degeneration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic atrophy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iris neovascularisation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatomegaly			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			

subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Thyroid mass			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cervical spinal stenosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facet joint syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 3 (0.00%)	5 / 215 (2.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 215 (1.86%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryocystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parapharyngeal space infection			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Nilotinib treatment consolidation (NTCS) phase	Nilotinib treatment-free remission (TFR) phase	Nilotinib treatment re-initiation (NTRI) phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	159 / 215 (73.95%)	136 / 190 (71.58%)	86 / 91 (94.51%)
Vascular disorders			
Hypertension			
subjects affected / exposed	17 / 215 (7.91%)	24 / 190 (12.63%)	14 / 91 (15.38%)
occurrences (all)	18	30	16
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 215 (2.33%)	9 / 190 (4.74%)	4 / 91 (4.40%)
occurrences (all)	5	11	4
Chest pain			
subjects affected / exposed	5 / 215 (2.33%)	5 / 190 (2.63%)	4 / 91 (4.40%)
occurrences (all)	5	5	4
Influenza like illness			
subjects affected / exposed	3 / 215 (1.40%)	6 / 190 (3.16%)	2 / 91 (2.20%)
occurrences (all)	3	11	3
Fatigue			
subjects affected / exposed	9 / 215 (4.19%)	7 / 190 (3.68%)	14 / 91 (15.38%)
occurrences (all)	9	7	15

Drug withdrawal syndrome subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Localised oedema subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	1 / 190 (0.53%) 1	0 / 91 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	2 / 215 (0.93%) 3	10 / 190 (5.26%) 11	3 / 91 (3.30%) 3
Pain subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	1 / 190 (0.53%) 1	3 / 91 (3.30%) 4
Pyrexia subjects affected / exposed occurrences (all)	7 / 215 (3.26%) 7	8 / 190 (4.21%) 8	1 / 91 (1.10%) 1
Reproductive system and breast disorders			
Erectile dysfunction subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	3 / 190 (1.58%) 3	2 / 91 (2.20%) 2
Menstruation irregular subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Penile pain subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	8 / 215 (3.72%) 9	12 / 190 (6.32%) 16	6 / 91 (6.59%) 6
Dysphonia subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	2 / 91 (2.20%) 2
Dyspnoea subjects affected / exposed occurrences (all)	6 / 215 (2.79%) 6	5 / 190 (2.63%) 5	5 / 91 (5.49%) 5
Oropharyngeal pain			

subjects affected / exposed occurrences (all)	4 / 215 (1.86%) 4	4 / 190 (2.11%) 4	3 / 91 (3.30%) 4
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	2 / 190 (1.05%) 2	1 / 91 (1.10%) 1
Pleural effusion subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	7 / 190 (3.68%) 7	3 / 91 (3.30%) 3
Depression subjects affected / exposed occurrences (all)	2 / 215 (0.93%) 2	4 / 190 (2.11%) 4	6 / 91 (6.59%) 7
Insomnia subjects affected / exposed occurrences (all)	2 / 215 (0.93%) 2	5 / 190 (2.63%) 5	3 / 91 (3.30%) 3
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	3 / 215 (1.40%) 3	4 / 190 (2.11%) 7	5 / 91 (5.49%) 6
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	2 / 215 (0.93%) 2	2 / 190 (1.05%) 4	3 / 91 (3.30%) 3
Blood bilirubin increased subjects affected / exposed occurrences (all)	4 / 215 (1.86%) 4	0 / 190 (0.00%) 0	3 / 91 (3.30%) 5
Blood cholesterol increased subjects affected / exposed occurrences (all)	6 / 215 (2.79%) 6	4 / 190 (2.11%) 5	9 / 91 (9.89%) 10
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	4 / 190 (2.11%) 4	2 / 91 (2.20%) 3
Blood pressure increased			

subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	2 / 215 (0.93%)	0 / 190 (0.00%)	2 / 91 (2.20%)
occurrences (all)	2	0	5
Blood triglycerides increased			
subjects affected / exposed	1 / 215 (0.47%)	4 / 190 (2.11%)	1 / 91 (1.10%)
occurrences (all)	1	4	1
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	7 / 215 (3.26%)	5 / 190 (2.63%)	17 / 91 (18.68%)
occurrences (all)	7	9	38
Weight decreased			
subjects affected / exposed	2 / 215 (0.93%)	8 / 190 (4.21%)	4 / 91 (4.40%)
occurrences (all)	2	10	5
Liver function test abnormal			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	2 / 215 (0.93%)	2 / 190 (1.05%)	1 / 91 (1.10%)
occurrences (all)	3	2	1
Chest injury			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Ear canal injury			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 215 (0.47%)	4 / 190 (2.11%)	0 / 91 (0.00%)
occurrences (all)	1	4	0
Fall			

subjects affected / exposed occurrences (all)	5 / 215 (2.33%) 5	2 / 190 (1.05%) 2	4 / 91 (4.40%) 5
Lip injury subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Cardiac disorders			
Angina pectoris subjects affected / exposed occurrences (all)	2 / 215 (0.93%) 2	0 / 190 (0.00%) 0	1 / 91 (1.10%) 1
Atrial fibrillation subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	2 / 190 (1.05%) 2	5 / 91 (5.49%) 6
Nervous system disorders			
Amnesia subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	4 / 215 (1.86%) 5	5 / 190 (2.63%) 5	1 / 91 (1.10%) 1
Carotid artery stenosis subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	1 / 91 (1.10%) 1
Encephalopathy subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	10 / 215 (4.65%) 16	23 / 190 (12.11%) 27	11 / 91 (12.09%) 17
Sciatica subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	6 / 190 (3.16%) 6	8 / 91 (8.79%) 8
Neuropathy peripheral subjects affected / exposed occurrences (all)	2 / 215 (0.93%) 2	1 / 190 (0.53%) 1	0 / 91 (0.00%) 0
Blood and lymphatic system disorders			

Anaemia subjects affected / exposed occurrences (all)	4 / 215 (1.86%) 5	8 / 190 (4.21%) 9	10 / 91 (10.99%) 14
Eye disorders			
Cataract subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	4 / 190 (2.11%) 6	1 / 91 (1.10%) 2
Dry eye subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	0 / 190 (0.00%) 0	2 / 91 (2.20%) 2
Vision blurred subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	3 / 215 (1.40%) 4	7 / 190 (3.68%) 12	5 / 91 (5.49%) 8
Abdominal hernia subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	1 / 190 (0.53%) 1	0 / 91 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	9 / 215 (4.19%) 10	9 / 190 (4.74%) 11	8 / 91 (8.79%) 11
Constipation subjects affected / exposed occurrences (all)	3 / 215 (1.40%) 3	6 / 190 (3.16%) 6	6 / 91 (6.59%) 7
Diarrhoea subjects affected / exposed occurrences (all)	12 / 215 (5.58%) 13	14 / 190 (7.37%) 15	5 / 91 (5.49%) 6
Gastritis subjects affected / exposed occurrences (all)	3 / 215 (1.40%) 3	2 / 190 (1.05%) 2	5 / 91 (5.49%) 6
Mouth ulceration			

subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	6 / 215 (2.79%)	4 / 190 (2.11%)	13 / 91 (14.29%)
occurrences (all)	7	4	13
Oral disorder			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 215 (0.00%)	2 / 190 (1.05%)	1 / 91 (1.10%)
occurrences (all)	0	2	2
Salivary gland calculus			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	6 / 215 (2.79%)	9 / 190 (4.74%)	8 / 91 (8.79%)
occurrences (all)	6	16	8
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	6 / 215 (2.79%)	5 / 190 (2.63%)	8 / 91 (8.79%)
occurrences (all)	6	5	9
Acne			
subjects affected / exposed	2 / 215 (0.93%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	2	0	0
Macule			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	2 / 215 (0.93%)	4 / 190 (2.11%)	6 / 91 (6.59%)
occurrences (all)	3	6	6
Dry skin			
subjects affected / exposed	5 / 215 (2.33%)	1 / 190 (0.53%)	3 / 91 (3.30%)
occurrences (all)	5	2	3
Keratosis pilaris			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0

Dermatitis			
subjects affected / exposed	0 / 215 (0.00%)	2 / 190 (1.05%)	1 / 91 (1.10%)
occurrences (all)	0	2	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	7 / 215 (3.26%)	4 / 190 (2.11%)	7 / 91 (7.69%)
occurrences (all)	7	4	9
Pruritus			
subjects affected / exposed	4 / 215 (1.86%)	2 / 190 (1.05%)	13 / 91 (14.29%)
occurrences (all)	5	2	18
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 215 (0.00%)	2 / 190 (1.05%)	1 / 91 (1.10%)
occurrences (all)	0	5	1
Urinary retention			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences (all)	0	0	1
Urinary tract obstruction			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	24 / 215 (11.16%)	44 / 190 (23.16%)	14 / 91 (15.38%)
occurrences (all)	27	67	18
Arthritis			
subjects affected / exposed	1 / 215 (0.47%)	2 / 190 (1.05%)	0 / 91 (0.00%)
occurrences (all)	1	2	0
Back pain			

subjects affected / exposed	8 / 215 (3.72%)	15 / 190 (7.89%)	11 / 91 (12.09%)
occurrences (all)	8	19	14
Bone pain			
subjects affected / exposed	3 / 215 (1.40%)	9 / 190 (4.74%)	1 / 91 (1.10%)
occurrences (all)	4	9	1
Bursitis			
subjects affected / exposed	0 / 215 (0.00%)	2 / 190 (1.05%)	0 / 91 (0.00%)
occurrences (all)	0	3	0
Intervertebral disc protrusion			
subjects affected / exposed	2 / 215 (0.93%)	6 / 190 (3.16%)	4 / 91 (4.40%)
occurrences (all)	2	7	5
Muscle spasms			
subjects affected / exposed	7 / 215 (3.26%)	7 / 190 (3.68%)	8 / 91 (8.79%)
occurrences (all)	8	10	8
Musculoskeletal chest pain			
subjects affected / exposed	0 / 215 (0.00%)	3 / 190 (1.58%)	2 / 91 (2.20%)
occurrences (all)	0	3	2
Myalgia			
subjects affected / exposed	3 / 215 (1.40%)	16 / 190 (8.42%)	9 / 91 (9.89%)
occurrences (all)	3	19	9
Pain in extremity			
subjects affected / exposed	7 / 215 (3.26%)	18 / 190 (9.47%)	3 / 91 (3.30%)
occurrences (all)	7	23	4
Osteoarthritis			
subjects affected / exposed	1 / 215 (0.47%)	8 / 190 (4.21%)	4 / 91 (4.40%)
occurrences (all)	1	9	5
Rotator cuff syndrome			
subjects affected / exposed	0 / 215 (0.00%)	2 / 190 (1.05%)	1 / 91 (1.10%)
occurrences (all)	0	2	2
Infections and infestations			
Bronchitis bacterial			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	8 / 215 (3.72%)	7 / 190 (3.68%)	2 / 91 (2.20%)
occurrences (all)	10	8	5

COVID-19			
subjects affected / exposed	0 / 215 (0.00%)	21 / 190 (11.05%)	7 / 91 (7.69%)
occurrences (all)	0	24	8
Furuncle			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	4 / 215 (1.86%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences (all)	4	0	1
Gastroenteritis			
subjects affected / exposed	4 / 215 (1.86%)	6 / 190 (3.16%)	4 / 91 (4.40%)
occurrences (all)	4	6	6
Gastrointestinal viral infection			
subjects affected / exposed	0 / 215 (0.00%)	1 / 190 (0.53%)	0 / 91 (0.00%)
occurrences (all)	0	2	0
Herpes ophthalmic			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	5 / 215 (2.33%)	5 / 190 (2.63%)	6 / 91 (6.59%)
occurrences (all)	6	6	7
Influenza			
subjects affected / exposed	6 / 215 (2.79%)	16 / 190 (8.42%)	6 / 91 (6.59%)
occurrences (all)	7	19	8
Laryngitis			
subjects affected / exposed	1 / 215 (0.47%)	3 / 190 (1.58%)	1 / 91 (1.10%)
occurrences (all)	1	4	1
Mucosal infection			
subjects affected / exposed	0 / 215 (0.00%)	0 / 190 (0.00%)	0 / 91 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	22 / 215 (10.23%)	32 / 190 (16.84%)	19 / 91 (20.88%)
occurrences (all)	27	72	63

Ophthalmic herpes zoster subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	0 / 190 (0.00%) 0	1 / 91 (1.10%) 1
Pharyngitis subjects affected / exposed occurrences (all)	2 / 215 (0.93%) 2	3 / 190 (1.58%) 3	4 / 91 (4.40%) 6
Pneumonia subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	4 / 190 (2.11%) 4	1 / 91 (1.10%) 1
Pustule subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Respiratory tract infection subjects affected / exposed occurrences (all)	2 / 215 (0.93%) 2	3 / 190 (1.58%) 3	1 / 91 (1.10%) 1
Sinusitis subjects affected / exposed occurrences (all)	3 / 215 (1.40%) 3	9 / 190 (4.74%) 20	4 / 91 (4.40%) 4
Sialoadenitis subjects affected / exposed occurrences (all)	0 / 215 (0.00%) 0	0 / 190 (0.00%) 0	1 / 91 (1.10%) 1
Skin infection subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	2 / 190 (1.05%) 2	1 / 91 (1.10%) 1
Upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 215 (3.26%) 8	18 / 190 (9.47%) 33	3 / 91 (3.30%) 6
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 215 (0.93%) 2	9 / 190 (4.74%) 17	7 / 91 (7.69%) 13
Wound infection subjects affected / exposed occurrences (all)	1 / 215 (0.47%) 1	0 / 190 (0.00%) 0	0 / 91 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite			

subjects affected / exposed	2 / 215 (0.93%)	3 / 190 (1.58%)	2 / 91 (2.20%)
occurrences (all)	2	3	2
Diabetes mellitus			
subjects affected / exposed	2 / 215 (0.93%)	2 / 190 (1.05%)	1 / 91 (1.10%)
occurrences (all)	2	2	1
Hypercholesterolaemia			
subjects affected / exposed	5 / 215 (2.33%)	6 / 190 (3.16%)	8 / 91 (8.79%)
occurrences (all)	5	7	17
Hyperglycaemia			
subjects affected / exposed	3 / 215 (1.40%)	4 / 190 (2.11%)	8 / 91 (8.79%)
occurrences (all)	3	5	14
Hyperlipidaemia			
subjects affected / exposed	0 / 215 (0.00%)	2 / 190 (1.05%)	3 / 91 (3.30%)
occurrences (all)	0	2	3
Hypertriglyceridaemia			
subjects affected / exposed	1 / 215 (0.47%)	7 / 190 (3.68%)	4 / 91 (4.40%)
occurrences (all)	1	11	5
Hypokalaemia			
subjects affected / exposed	1 / 215 (0.47%)	0 / 190 (0.00%)	1 / 91 (1.10%)
occurrences (all)	1	0	1
Hypophosphataemia			
subjects affected / exposed	16 / 215 (7.44%)	3 / 190 (1.58%)	12 / 91 (13.19%)
occurrences (all)	20	3	22

Non-serious adverse events	Nilotinib treatment continuation (NTCT) phase	Nilotinib treatment-free remission-2 (TFR-2) phase	Nilotinib treatment re-initiation-2 (NTRI-2) phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 13 (84.62%)	7 / 10 (70.00%)	5 / 5 (100.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 13 (15.38%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	2	1	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	1 / 13 (7.69%)	2 / 10 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Fatigue			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Drug withdrawal syndrome			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Localised oedema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	2
Oedema peripheral			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Menstruation irregular			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Penile pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 10 (10.00%) 1	3 / 5 (60.00%) 4
Dysphonia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 2
Pleural effusion subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Depression subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 10 (10.00%) 2	1 / 5 (20.00%) 1
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Blood bilirubin increased			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Blood pressure increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood triglycerides increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	3
Weight decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Chest injury			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
Ear canal injury subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Ligament sprain subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Fall subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
Lip injury subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Cardiac disorders Angina pectoris subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Nervous system disorders Amnesia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Carotid artery stenosis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Encephalopathy subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Headache			

subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 10 (10.00%) 1	2 / 5 (40.00%) 2
Sciatica subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 2
Eye disorders Cataract subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Dry eye subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Vision blurred subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Abdominal hernia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Abdominal distension subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Constipation			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oral disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Salivary gland calculus			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Acne			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Macule			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Eczema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Keratosis pilaris			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	2 / 13 (15.38%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	2
Pruritus			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Polyuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Urinary tract obstruction			

subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 13 (7.69%)	3 / 10 (30.00%)	2 / 5 (40.00%)
occurrences (all)	2	3	3
Arthritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 10 (10.00%)	1 / 5 (20.00%)
occurrences (all)	2	2	1
Bone pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	1 / 13 (7.69%)	2 / 10 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	3	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	4
Osteoarthritis			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Rotator cuff syndrome subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Infections and infestations			
Bronchitis bacterial subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Bronchitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1	1 / 5 (20.00%) 1
COVID-19 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1	1 / 5 (20.00%) 1
Furuncle subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Folliculitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
Gastroenteritis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 10 (10.00%) 1	1 / 5 (20.00%) 1
Gastrointestinal viral infection subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Herpes ophthalmic subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
Genital infection fungal subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 10 (10.00%) 1	0 / 5 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0

Influenza			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Mucosal infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	3
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pustule			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	2 / 5 (40.00%)
occurrences (all)	0	1	2
Sialoadenitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 10 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 10 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	1 / 5 (20.00%) 4
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Wound infection subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 2
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	3 / 13 (23.08%) 3	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	1 / 5 (20.00%) 1
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 10 (0.00%) 0	0 / 5 (0.00%) 0

Non-serious adverse events	Nilotinib treatment prolonged continuation (NTCT -	All patients	
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	P) phase		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	205 / 215 (95.35%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	51 / 215 (23.72%)	
occurrences (all)	0	68	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	17 / 215 (7.91%)	
occurrences (all)	0	20	
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	15 / 215 (6.98%)	
occurrences (all)	0	15	
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	13 / 215 (6.05%)	
occurrences (all)	0	20	
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	25 / 215 (11.63%)	
occurrences (all)	0	32	
Drug withdrawal syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences (all)	0	2	
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences (all)	0	4	
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	15 / 215 (6.98%)	
occurrences (all)	0	18	
Pain			
subjects affected / exposed	0 / 3 (0.00%)	5 / 215 (2.33%)	
occurrences (all)	0	6	
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	16 / 215 (7.44%)	
occurrences (all)	0	17	
Reproductive system and breast disorders			

Erectile dysfunction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	7 / 215 (3.26%) 7	
Menstruation irregular subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 215 (0.93%) 2	
Penile pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 215 (0.47%) 1	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	30 / 215 (13.95%) 37	
Dysphonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	3 / 215 (1.40%) 3	
Dyspnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	15 / 215 (6.98%) 18	
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	12 / 215 (5.58%) 13	
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	4 / 215 (1.86%) 5	
Pleural effusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 215 (0.47%) 1	
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	11 / 215 (5.12%) 13	
Depression subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	12 / 215 (5.58%) 16	
Insomnia			

subjects affected / exposed	0 / 3 (0.00%)	11 / 215 (5.12%)	
occurrences (all)	0	13	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	13 / 215 (6.05%)	
occurrences (all)	0	17	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	8 / 215 (3.72%)	
occurrences (all)	0	10	
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	7 / 215 (3.26%)	
occurrences (all)	6	15	
Blood cholesterol increased			
subjects affected / exposed	1 / 3 (33.33%)	19 / 215 (8.84%)	
occurrences (all)	2	24	
Blood creatinine increased			
subjects affected / exposed	1 / 3 (33.33%)	8 / 215 (3.72%)	
occurrences (all)	1	11	
Blood pressure increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences (all)	0	2	
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	4 / 215 (1.86%)	
occurrences (all)	0	8	
Blood triglycerides increased			
subjects affected / exposed	1 / 3 (33.33%)	6 / 215 (2.79%)	
occurrences (all)	3	10	
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences (all)	0	2	
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	28 / 215 (13.02%)	
occurrences (all)	0	57	
Weight decreased			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	11 / 215 (5.12%) 17	
Liver function test abnormal subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 215 (0.47%) 1	
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	6 / 215 (2.79%) 7	
Chest injury subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 215 (0.47%) 1	
Ear canal injury subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 215 (0.47%) 1	
Ligament sprain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	6 / 215 (2.79%) 7	
Fall subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	11 / 215 (5.12%) 14	
Lip injury subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 215 (0.47%) 1	
Cardiac disorders			
Angina pectoris subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	4 / 215 (1.86%) 4	
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	8 / 215 (3.72%) 9	
Nervous system disorders			
Amnesia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 215 (0.47%) 1	
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	11 / 215 (5.12%)	
occurrences (all)	0	12	
Carotid artery stenosis			
subjects affected / exposed	1 / 3 (33.33%)	3 / 215 (1.40%)	
occurrences (all)	1	3	
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	0 / 3 (0.00%)	42 / 215 (19.53%)	
occurrences (all)	0	64	
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	16 / 215 (7.44%)	
occurrences (all)	0	16	
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	4 / 215 (1.86%)	
occurrences (all)	0	4	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	19 / 215 (8.84%)	
occurrences (all)	0	30	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	6 / 215 (2.79%)	
occurrences (all)	0	9	
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	4 / 215 (1.86%)	
occurrences (all)	0	4	
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	14 / 215 (6.51%)	
occurrences (all)	0	24	
Abdominal hernia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)
occurrences (all)	0	1
Abdominal distension		
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)
occurrences (all)	0	2
Abdominal pain upper		
subjects affected / exposed	0 / 3 (0.00%)	21 / 215 (9.77%)
occurrences (all)	0	32
Constipation		
subjects affected / exposed	0 / 3 (0.00%)	15 / 215 (6.98%)
occurrences (all)	0	17
Diarrhoea		
subjects affected / exposed	0 / 3 (0.00%)	30 / 215 (13.95%)
occurrences (all)	0	35
Gastritis		
subjects affected / exposed	0 / 3 (0.00%)	9 / 215 (4.19%)
occurrences (all)	0	11
Mouth ulceration		
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)
occurrences (all)	0	2
Nausea		
subjects affected / exposed	0 / 3 (0.00%)	22 / 215 (10.23%)
occurrences (all)	0	25
Oral disorder		
subjects affected / exposed	1 / 3 (33.33%)	1 / 215 (0.47%)
occurrences (all)	1	1
Periodontal disease		
subjects affected / exposed	0 / 3 (0.00%)	4 / 215 (1.86%)
occurrences (all)	0	5
Salivary gland calculus		
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)
occurrences (all)	0	2
Vomiting		
subjects affected / exposed	0 / 3 (0.00%)	21 / 215 (9.77%)
occurrences (all)	0	30
Skin and subcutaneous tissue disorders		

Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	19 / 215 (8.84%)	
occurrences (all)	0	21	
Acne			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences (all)	0	3	
Macule			
subjects affected / exposed	1 / 3 (33.33%)	1 / 215 (0.47%)	
occurrences (all)	1	1	
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	12 / 215 (5.58%)	
occurrences (all)	0	15	
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	8 / 215 (3.72%)	
occurrences (all)	0	12	
Keratosis pilaris			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences (all)	0	1	
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 215 (1.86%)	
occurrences (all)	0	4	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	0 / 3 (0.00%)	20 / 215 (9.30%)	
occurrences (all)	0	24	
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	19 / 215 (8.84%)	
occurrences (all)	0	26	
Renal and urinary disorders			
Bladder spasm			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences (all)	0	1	
Polyuria			

subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences (all)	0	2	
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	4 / 215 (1.86%)	
occurrences (all)	0	7	
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences (all)	0	2	
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	73 / 215 (33.95%)	
occurrences (all)	0	120	
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 215 (1.86%)	
occurrences (all)	0	4	
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	32 / 215 (14.88%)	
occurrences (all)	0	46	
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	12 / 215 (5.58%)	
occurrences (all)	0	14	
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences (all)	0	4	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 3 (0.00%)	13 / 215 (6.05%)	
occurrences (all)	0	15	
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	20 / 215 (9.30%)	
occurrences (all)	0	30	
Musculoskeletal chest pain			

subjects affected / exposed	0 / 3 (0.00%)	6 / 215 (2.79%)	
occurrences (all)	0	6	
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	28 / 215 (13.02%)	
occurrences (all)	0	33	
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	30 / 215 (13.95%)	
occurrences (all)	0	38	
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	12 / 215 (5.58%)	
occurrences (all)	0	15	
Rotator cuff syndrome			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences (all)	0	5	
Infections and infestations			
Bronchitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)	
occurrences (all)	0	1	
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	18 / 215 (8.37%)	
occurrences (all)	0	25	
COVID-19			
subjects affected / exposed	1 / 3 (33.33%)	31 / 215 (14.42%)	
occurrences (all)	1	35	
Furuncle			
subjects affected / exposed	1 / 3 (33.33%)	2 / 215 (0.93%)	
occurrences (all)	1	2	
Folliculitis			
subjects affected / exposed	1 / 3 (33.33%)	7 / 215 (3.26%)	
occurrences (all)	1	7	
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	15 / 215 (6.98%)	
occurrences (all)	0	19	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences (all)	0	3	

Herpes ophthalmic		
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)
occurrences (all)	0	1
Genital infection fungal		
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)
occurrences (all)	0	1
Herpes zoster		
subjects affected / exposed	0 / 3 (0.00%)	14 / 215 (6.51%)
occurrences (all)	0	19
Influenza		
subjects affected / exposed	0 / 3 (0.00%)	25 / 215 (11.63%)
occurrences (all)	0	35
Laryngitis		
subjects affected / exposed	0 / 3 (0.00%)	6 / 215 (2.79%)
occurrences (all)	0	7
Mucosal infection		
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)
occurrences (all)	0	1
Nasopharyngitis		
subjects affected / exposed	0 / 3 (0.00%)	58 / 215 (26.98%)
occurrences (all)	0	165
Ophthalmic herpes zoster		
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)
occurrences (all)	0	3
Pharyngitis		
subjects affected / exposed	0 / 3 (0.00%)	9 / 215 (4.19%)
occurrences (all)	0	12
Pneumonia		
subjects affected / exposed	1 / 3 (33.33%)	6 / 215 (2.79%)
occurrences (all)	1	6
Pustule		
subjects affected / exposed	0 / 3 (0.00%)	1 / 215 (0.47%)
occurrences (all)	0	1
Respiratory tract infection		
subjects affected / exposed	0 / 3 (0.00%)	7 / 215 (3.26%)
occurrences (all)	0	7

Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	17 / 215 (7.91%)	
occurrences (all)	0	30	
Sialoadenitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences (all)	0	2	
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	5 / 215 (2.33%)	
occurrences (all)	0	5	
Upper respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	28 / 215 (13.02%)	
occurrences (all)	2	54	
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	18 / 215 (8.37%)	
occurrences (all)	0	33	
Wound infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 215 (0.93%)	
occurrences (all)	0	3	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	8 / 215 (3.72%)	
occurrences (all)	0	8	
Diabetes mellitus			
subjects affected / exposed	1 / 3 (33.33%)	6 / 215 (2.79%)	
occurrences (all)	1	6	
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	16 / 215 (7.44%)	
occurrences (all)	0	29	
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	14 / 215 (6.51%)	
occurrences (all)	0	23	
Hyperlipidaemia			
subjects affected / exposed	0 / 3 (0.00%)	6 / 215 (2.79%)	
occurrences (all)	0	6	
Hypertriglyceridaemia			

subjects affected / exposed	0 / 3 (0.00%)	14 / 215 (6.51%)	
occurrences (all)	0	20	
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 215 (1.40%)	
occurrences (all)	0	3	
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	24 / 215 (11.16%)	
occurrences (all)	0	45	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 July 2013	<p>Amendment 1: Primary purpose for the amendment was:</p> <ul style="list-style-type: none">• To implement modifications as requested from different Health Authorities (HAs) and Ethic Committees/Institutional Review Boards (ECs/IRBs) during review of the original protocol.• To address feedback from Investigators received during the study startup
03 July 2014	<p>Amendment 2: The main purposes of the amendment were:</p> <ul style="list-style-type: none">• To include cholesterol testing in the assessment schedule. Elevations in total serum cholesterol and low density lipoprotein cholesterol have been observed very commonly (more than 10 %) in patients treated with nilotinib and commonly (between 1 to 10 %) in patients treated with imatinib. To provide a harmonization on dose reductions guidelines across Novartis-sponsored Tassigna study protocols Hence the dose reduction guidelines for the following nonhematologic toxicities have been updated:• Pancreatitis Grade 4: change from "Hold therapy" to "Stop therapy"• QTcF prolongation > 480 msec toxicity• Cardiac "Other": change from "Hold therapy" to "Stop therapy"• To incorporate guidance for the management of:• Serum cholesterol increases• Blood glucose increases• Other cardiac risk factors• Ischemic vascular or ischemic cardiovascular events occurring in patients treated with nilotinib.• To incorporate precaution of use for antacid drugs to be aligned with Tassigna® FDA Prescribing Information and EMA SmPC.• To define ischemic vascular and ischemic cardiovascular events as Adverse Events of special interest, and their reporting.• To include serum phosphate testing in the assessment schedule to ensure consistency with the dose reduction guidelines provided in Table 6-2 in case of serum hypophosphatemia.• To clarify the specification of the statistical alternative hypothesis H1 in section 10.• To inform the IRBs/IECs/REBs and HAs about over-recruitment and its impact on the stopping rules applied to the first 48 weeks after start of TFR and on the sample size calculation in section 10.8.• To correct discrepancies and add clarifications within the protocol.

30 July 2015	<p>Amendment 3: The main purposes of the amendment were:</p> <p>To clarify instructions on when intensified PCR bi-weekly monitoring will be ended if loss of MR4.0 happened after the first 48 weeks of the TFR phase.</p> <p>To more precisely define "immediate" treatment re-initiation after loss of MMR.</p> <p>To further clarify the early study termination rules during the first 48 weeks of the TFR phase.</p> <p>To add a section "General non-hematological laboratory toxicity" to allow for a distinction from "General non-hematology toxicity", for which the described rules must be strictly applied without any possibility of modification by the investigator.</p> <p>To clarify that strong CYP3A4 inhibitors and QT interval prolonging agents are considered as prohibited concomitant medications during the whole duration of the study.</p> <p>To include retrospective collection of Sokal risk category at diagnosis parameters.</p> <p>To introduce additional guidance for investigators to differentiate between patients who discontinue certain clinical trial protocol elements (e.g., discontinue study treatment, or some or all visits etc), who withdraw consent or who are lost to follow-up.</p>
30 March 2016	<p>Amendment 4: The primary purpose for the amendment was:</p> <p>To include hepatitis B virus testing as one of the study procedures, to identify study patients who may be at risk of hepatitis B reactivation. Reactivation of hepatitis B virus can occur in patients who are chronic carriers of this virus and are receiving a drug of the BCR-ABL TKI class such as nilotinib. Some cases involving BCR-ABL TKI resulted in acute hepatic failure or fulminant hepatitis leading to liver transplantation or a fatal outcome.</p>
15 November 2016	<p>Amendment 5: The primary purposes of the amendment were:</p> <p>To extend the study duration to a minimum of 5 calendar years (264 weeks) after last patient entered the TFR phase and to include the corresponding analysis of data after nilotinib discontinuation, to confirm stability of the rate of patients staying in the TFR phase.</p> <p>To add a Treatment Free Survival (TFS) sensitivity analysis to consider discontinuation from the TFR phase due to any reason as a TFS event.</p> <p>To clarify that the testing of LDL-C, which is currently restricted to the calculated LDL-C parameter in the protocol, may also include the direct LDL-C parameter. Since protocol amendment 2, direct LDL-C is automatically measured and reported to sites for blood samples with a triglycerides value above 400mg/dL or 4.52mmol/L, for which the central laboratory cannot provide a calculated LDL-C value.</p> <p>To update Section 6.4.3 Prohibited concomitant therapy to bring clarity on action to be performed when QT prolonging drugs are taken depending on the risk category of Torsades de Pointe.</p>
27 April 2018	<p>Amendment 6: The primary purposes of the amendment were: To extend the study duration by a further period of 5 years to a minimum of 528 weeks (10 calendar years) after last patient entered the treatment-free remission (TFR) phase in order to confirm stability of the rate of patients remaining in the TFR phase and to evaluate the long-term safety and potential risk of resistance to treatment after nilotinib discontinuation, by collecting information on late relapses, loss of response and occurrence of mutations (risk of developing resistance).</p> <p>To evaluate the percentage of patients who are in stable response (MMR and MR4.5) after achievement of that response in nilotinib re-initiation phase for 48 weeks, 96 weeks, 144 weeks, 192 weeks, 240 weeks, 288 weeks, 336 weeks, 384 weeks and 432 weeks, based on availability of appropriate data.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.nov> for complete trial results.

Notes: