



## Clinical trial results:

**A phase 3, multi-center, open-label, randomized study of oral ABL001 versus bosutinib in patients with Chronic Myelogenous Leukemia in chronic phase (CML-CP), previously treated with 2 or more tyrosine kinase inhibitors**

### Summary

EudraCT number	2016-002461-66
Trial protocol	HU CZ ES BG DE GB FR NL BE IT RO
Global end of trial date	04 December 2024

### Results information

Result version number	v1 (current)
This version publication date	14 December 2025
First version publication date	14 December 2025

### Trial information

#### Trial identification

Sponsor protocol code	CABL001A2301
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03106779
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	Novartis Pharma, AG
Sponsor organisation address	Lichtstrasse 35, Basel, Switzerland, 4056
Public contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.com

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 December 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	04 December 2024
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To compare the MMR rate at 24 weeks of asciminib versus bosutinib

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> 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	26 October 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 7
Country: Number of subjects enrolled	Australia: 7
Country: Number of subjects enrolled	Brazil: 19
Country: Number of subjects enrolled	Bulgaria: 3
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Czechia: 2
Country: Number of subjects enrolled	France: 17
Country: Number of subjects enrolled	Germany: 18
Country: Number of subjects enrolled	Hungary: 3
Country: Number of subjects enrolled	Israel: 2
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Japan: 16
Country: Number of subjects enrolled	Korea, Republic of: 11
Country: Number of subjects enrolled	Lebanon: 3

Country: Number of subjects enrolled	Mexico: 1
Country: Number of subjects enrolled	Netherlands: 7
Country: Number of subjects enrolled	Romania: 4
Country: Number of subjects enrolled	Russian Federation: 33
Country: Number of subjects enrolled	Saudi Arabia: 5
Country: Number of subjects enrolled	Serbia: 3
Country: Number of subjects enrolled	Spain: 11
Country: Number of subjects enrolled	Switzerland: 2
Country: Number of subjects enrolled	Türkiye: 10
Country: Number of subjects enrolled	United Kingdom: 15
Country: Number of subjects enrolled	United States: 22
Worldwide total number of subjects	233
EEA total number of subjects	72

Notes:

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### 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)	189
From 65 to 84 years	44
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Participants were treated at a total of 84 sites.

### Pre-assignment

Screening details:

Randomization was stratified by major cytogenetic response (MCyR) at screening.

### Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Asciminib
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Arm description:

Participants randomized to asciminib 40mg BID

Arm type	Experimental
Investigational medicinal product name	Asciminib
Investigational medicinal product code	ABL001
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Asciminib 40 mg (20 mg and 40 mg dose strength tablets) was taken orally with a twice daily (BID) fasted.

<b>Arm title</b>	Bosutinib
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Arm description:

Participants randomized to bosutinib 500mg QD

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

Dosage and administration details:

Bosutinib 500 mg (100 mg and 500 mg dose strength tablets) was taken once daily (QD) fed dosing.

Number of subjects in period 1	Asciminib	Bosutinib
Started	157	76
Treated	156	76
Not Treated	1 <sup>[1]</sup>	0 <sup>[2]</sup>
Switched to receive asciminib	0 <sup>[3]</sup>	25

Completed	77	8
Not completed	80	68
Adverse event, serious fatal	4	-
Physician decision	13	7
Adverse event, non-fatal	11	21
Progressive Disease	2	3
Pregnancy	1	-
Subject/Guardian Decision	6	7
Lost to follow-up	1	2
Lack of efficacy	40	28
Protocol deviation	1	-
Not treated	1	-

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Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Added just for clarification

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Added just for clarification

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Added just for clarification

## Baseline characteristics

### Reporting groups

Reporting group title	Asciminib
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Reporting group description:

Participants randomized to asciminib 40mg BID

Reporting group title	Bosutinib
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Reporting group description:

Participants randomized to bosutinib 500mg QD

Reporting group values	Asciminib	Bosutinib	Total
Number of subjects	157	76	233
Age categorical			
Units: Subjects			
Adults (18-64 years)	128	61	189
From 65-84 years	29	15	44
Age Continuous			
Units: years			
arithmetic mean	51.0	51.0	
standard deviation	± 13.49	± 13.95	-
Sex: Female, Male			
Units: participants			
Female	75	45	120
Male	82	31	113
Race/Ethnicity, Customized			
Units: Subjects			
White	118	56	174
Asian	22	11	33
Black or African American	8	2	10
American Indian or Alaska Native	1	0	1
Other	5	7	12
Unknown	3	0	3

## End points

### End points reporting groups

Reporting group title	Asciminib
Reporting group description:	
Participants randomized to asciminib 40mg BID	
Reporting group title	Bosutinib
Reporting group description:	
Participants randomized to bosutinib 500mg QD	

### Primary: Major Molecular Response (MMR) rate at 24 weeks

End point title	Major Molecular Response (MMR) rate at 24 weeks
End point description:	
MMR was defined as a $\geq 3.0$ log reduction in BCR-ABL1 transcripts compared to the standardized baseline equivalent to $\leq 0.1\%$ BCR-ABL1/ABL% by international scale (IS) as measured by RQ-PCR.	
End point type	Primary
End point timeframe:	
24 weeks	

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	76		
Units: Percentage of participants				
number (not applicable)	25.48	13.16		

### Statistical analyses

Statistical analysis title	Analysis for MMR at 24 weeks
Comparison groups	Asciminib v Bosutinib
Number of subjects included in analysis	233
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.029
Method	Cochran-Mantel-Haenszel
Parameter estimate	treatment difference in the MMR rate
Point estimate	12.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.19
upper limit	22.3

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**Secondary: Major Molecular Response (MMR) rate at 96 weeks (Key secondary endpoint)**

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End point title	Major Molecular Response (MMR) rate at 96 weeks (Key secondary endpoint)
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End point description:

MMR at 96 weeks was defined as the percentage of participants with MMR at 96 weeks. MMR was defined as a  $\geq 3.0$  log reduction in BCR-ABL1 transcripts compared to the standardized baseline equivalent to  $\leq 0.1\%$  BCR-ABL1/ABL% by international scale (IS) as measured by RQ-PCR.

End point type	Secondary
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End point timeframe:

96 Weeks

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End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	76		
Units: Percentage of participants				
number (not applicable)	35.78	15.79		

**Statistical analyses**

<b>Statistical analysis title</b>	MMR at 96 weeks
Comparison groups	Asciminib v Bosutinib
Number of subjects included in analysis	233
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Cochran-Mantel- Haenszel chi-square test
Point estimate	21.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.53
upper limit	32.95

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**Secondary: Complete Cytogenetic Response (CCyR) rate at scheduled time points**

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End point title	Complete Cytogenetic Response (CCyR) rate at scheduled time points
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End point description:

Cytogenetic response included Complete, Partial, Major, Minor, Minimal and no response. Cytogenetic response was assessed as the percentage of Ph+ metaphases in the bone marrow and is defined as the following: Complete (CCyR) - 0% Ph+ metaphases; Partial (PCyR) - >0 to 35% Ph+ metaphases; Major



(MCyR) - 0 to 35% Ph+ metaphases; Minor (mCyR) - >35 to 65% Ph+ metaphases; Minimal - >65 to 95% Ph+ metaphases; None - >95 to 100% Ph+ metaphases.

End point type	Secondary
End point timeframe:	
at 24, 48, 72, 96, 120 and 144 weeks	

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	62		
Units: Participants				
at Week 24	42	15		
at Week 48	41	13		
at Week 72	39	12		
at Week 96	41	10		
at Week 120	37	7		
at Week 144	35	4		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Complete Cytogenetic Response rate by scheduled time points

End point title	Complete Cytogenetic Response rate by scheduled time points
End point description:	
Cytogenetic response included Complete, Partial, Major, Minor, Minimal and no response. Cytogenetic response was assessed as the percentage of Ph+ metaphases in the bone marrow and is defined as the following: Complete (CCyR) - 0% Ph+ metaphases; Partial (PCyR) - >0 to 35% Ph+ metaphases; Major (MCyR) - 0 to 35% Ph+ metaphases; Minor (mCyR) - >35 to 65% Ph+ metaphases; Minimal - >65 to 95% Ph+ metaphases; None - >95 to 100% Ph+ metaphases.	
End point type	Secondary
End point timeframe:	
by 24, 48, 72, 96, 120 and 144 weeks	

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	62		
Units: Participants				
by Week 24	42	15		
by Week 48	47	22		
by Week 72	49	22		
by Week 96	51	22		
by Week 120	51	22		
by Week 144	51	22		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Major Molecular Response (MMR) rate at all scheduled data collection time points except Weeks 24 & 96

End point title	Major Molecular Response (MMR) rate at all scheduled data collection time points except Weeks 24 & 96
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End point description:

MMR was defined as a  $\geq 3.0$  log reduction in BCR-ABL1 transcripts compared to the standardized baseline equivalent to  $\leq 0.1\%$  BCR-ABL1/ABL% by international scale (IS) as measured by RQ-PCR.

End point type	Secondary
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End point timeframe:

at Weeks 36, 48, 60, 72, 84, 108, 120, 132, 144 & 156

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	76		
Units: Participants				
at Week 36	41	9		
at Week 48	46	10		
at Week 60	52	11		
at Week 72	52	12		
at Week 84	50	10		
at Week 108	53	11		
at Week 120	57	8		
at Week 132	58	8		
at Week 144	59	7		
at Week 156	53	8		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Major Molecular Response (MMR) rate by all scheduled data collection time points

End point title	Major Molecular Response (MMR) rate by all scheduled data collection time points
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End point description:

MMR was defined as a  $\geq 3.0$  log reduction in BCR-ABL1 transcripts compared to the standardized baseline equivalent to  $\leq 0.1\%$  BCR-ABL1/ABL% by international scale (IS) as measured by RQ-PCR.

Overall time point has the count indicating participants achieving MMR at any time during the study.

End point type	Secondary
End point timeframe:	
by Weeks 4, 8, 12, 16, 24, 36, 48, 60, 72, 84, 96, 108, 120, 132, 144 & 156, Overall	

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	76		
Units: Participants				
by Week 4	3	0		
by Week 8	12	4		
by Week 12	30	7		
by Week 16	39	8		
by Week 24	43	11		
by Week 36	51	13		
by Week 48	55	15		
by Week 60	60	16		
by Week 72	60	17		
by Week 84	63	17		
by Week 96	67	18		
by Week 108	67	18		
by Week 120	68	18		
by Week 132	70	18		
by Week 144	71	18		
by Week 156	71	18		
Overall	74	19		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Major Molecular Response (MMR)

End point title	Time to Major Molecular Response (MMR)
End point description:	
Time to MMR was defined as the time from the date of randomization to the date of the first documented MMR.	
End point type	Secondary
End point timeframe:	
216 Weeks	

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	19		
Units: Weeks				
median (full range (min-max))	16.3 (4 to 216)	24.1 (7 to 216)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Duration of Major Molecular Response (MMR)

End point title	Duration of Major Molecular Response (MMR)
End point description: Duration of MMR was defined as the time from the date of first documented MMR to the earliest date of loss of MMR, progression to Accelerated phase (AP) or Blast crisis (BC), or Chronic myeloid leukemia (CML)-related death.	
End point type	Secondary
End point timeframe: 216 Weeks	

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	74	19		
Units: Weeks				
median (full range (min-max))	999 (999 to 999)	999 (999 to 999)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Time to Complete Cytogenetic Response Rate (CCyR) among participants who achieved CCyR

End point title	Time to Complete Cytogenetic Response Rate (CCyR) among participants who achieved CCyR
End point description: Time to CCyR was defined as the time from the date of randomization to the date of the first documented CCyR.	
End point type	Secondary
End point timeframe: 216 Weeks	

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	22		
Units: Weeks				
median (full range (min-max))	24.3 (23 to 216)	24.3 (12 to 53)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Duration of Complete Cytogenetic Response (CCyR)

End point title	Duration of Complete Cytogenetic Response (CCyR)
End point description:	
Duration of CCyR was defined as the time between date of first documented CCyR and the earliest date of loss of CCyR, progression to AP/BC, or CML-related death for participants in the Cytogenetic Responder Set. The time was censored at the last cytogenetic assessment date on treatment for participants for whom none of the events was reported or last PCR evaluation on treatment indicating MMR.	
End point type	Secondary
End point timeframe:	
144 weeks	

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	22		
Units: Weeks				
median (full range (min-max))	999 (999 to 999)	99 (64.1 to 999)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Time to treatment failure (TTF)

End point title	Time to treatment failure (TTF)
End point description:	
TTF was defined as the time from date of randomization to an event of treatment failure. Treatment failure was defined as meeting a lack of efficacy criterion or discontinuing treatment due to any reason.	
End point type	Secondary
End point timeframe:	
156 Weeks	

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	76		
Units: Year				
median (confidence interval 95%)	2.4 (1.0 to 999)	0.5 (0.5 to 0.6)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Progression free survival per Kaplan-Meier event free estimates

End point title	Progression free survival per Kaplan-Meier event free estimates
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End point description:

Progression-free survival was defined as the time from the date of randomization to the earliest occurrence of documented disease progression to AP/BC or the date of death from any cause (including progressions and deaths observed during the survival follow-up period), per Kaplan-Meier.

End point type	Secondary
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End point timeframe:

5 years after the last patient enrolled into the study receives the first dose of the randomized treatment

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	76		
Units: Years				
median (confidence interval 95%)	5.6 (4.6 to 999)	5.0 (3.6 to 999)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Overall survival (OS)

End point title	Overall survival (OS)
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End point description:

Overall survival is defined as the time from the date of randomization to the date of death (including the survival follow-up period) per Kaplan-Meier (KM).

End point type	Secondary
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End point timeframe:

5 years after the last patient enrolled into the study receives the first dose of the randomized treatment

End point values	Asciminib	Bosutinib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	76		
Units: Years				
median (confidence interval 95%)	999 (999 to 999)	99 (6.3 to 999)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Trough plasma concentrations for asciminib

End point title	Trough plasma concentrations for asciminib <sup>[1]</sup>
End point description:	Measured concentration at the end of a dosing interval at steady state (taken directly before next administration)
End point type	Secondary
End point timeframe:	Week 2 Day 1 at: 0hr (pre-dose), 0.5hr, 1hr, 2hr, 3hr, 4hr, 6hr, 8hr & 12hr post-dose

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: Analysis for this endpoint was not planned

End point values	Asciminib			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: ng/mL				
median (full range (min-max))	238 (145 to 551)			

## Statistical analyses

No statistical analyses for this end point

### Secondary: PK parameter: Cmax for asciminib

End point title	PK parameter: Cmax for asciminib <sup>[2]</sup>
End point description:	Maximum (peak) observed plasma concentration after dose administration (mass x volume-1).
End point type	Secondary
End point timeframe:	Week 2 Day 1 at pre-dose, 0.5hr, 1hr, 2hr, 3hr, 4hr, 6hr, 8hr & 12hr post-dose

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: Analysis for this endpoint was not planned

End point values	Asciminib			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	971 ( $\pm$ 48.3)			

## Statistical analyses

No statistical analyses for this end point

### Secondary: PK parameter: Tmax for asciminib

End point title	PK parameter: Tmax for asciminib <sup>[3]</sup>
End point description: Time to reach maximum (peak) plasma concentration after dose administration (time). Actual sampling times were taken into consideration for the pharmacokinetic analysis.	
End point type	Secondary
End point timeframe: Week 2 Day 1 at: 0hr (pre-dose), 0.5hr, 1hr, 2hr, 3hr, 4hr, 6hr, 8hr & 12hr post-dose	

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: Analysis for this endpoint was not planned

End point values	Asciminib			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: hour (hr)				
median (full range (min-max))	1.92 (0.983 to 3.33)			

## Statistical analyses

No statistical analyses for this end point

### Secondary: PK parameter: AUC0-12h for asciminib

End point title	PK parameter: AUC0-12h for asciminib <sup>[4]</sup>
End point description: Area under the plasma concentration-time curve from time zero to 12 hours (mass x time x volume-1)	
End point type	Secondary
End point timeframe: Week 2 Day 1 at: 0hr (pre-dose), 0.5hr, 1hr, 2hr, 3hr, 4hr, 6hr, 8hr & 12hr post-dose	



Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: Analysis for this endpoint was not planned

End point values	Asciminib			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	5810 ( $\pm$ 32.9)			

## Statistical analyses

No statistical analyses for this end point

## Secondary: PK parameter: CL/F for asciminib

End point title	PK parameter: CL/F for asciminib <sup>[5]</sup>
End point description:	
Total apparent body clearance of drug from the plasma after oral administration (volume x time-1).	
End point type	Secondary
End point timeframe:	
Week 2 day 1 at: 0hr (pre-dose), 0.5hr, 1hr, 2hr, 3hr, 4hr, 6hr, 8hr & 12hr post-dose	

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: Analysis for this endpoint was not planned

End point values	Asciminib			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: L/hr				
median (full range (min-max))	7.29 (3.73 to 11.5)			

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Timeframe for AE

Adverse event reporting additional description:

AE additional description

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.0
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### Reporting groups

Reporting group title	Bosutinib
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Reporting group description:

Bosutinib

Reporting group title	Asciminib
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Reporting group description:

Asciminib

Serious adverse events	Bosutinib	Asciminib	
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 76 (27.63%)	34 / 156 (21.79%)	
number of deaths (all causes)	1	5	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			

subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal metastasis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
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	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic occlusion			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			

Complication associated with device			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pyrexia			
subjects affected / exposed	1 / 76 (1.32%)	2 / 156 (1.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthermia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
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			
Respiratory failure			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	3 / 76 (3.95%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device malfunction			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Ejection fraction decreased			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Femoral neck fracture			
subjects affected / exposed	1 / 76 (1.32%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			

subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
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	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
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	1 / 76 (1.32%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
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 / 76 (0.00%)	3 / 156 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure congestive			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral disorder			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Central nervous system vasculitis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			

subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic headache			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Toxic optic neuropathy			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			



Abdominal pain			
subjects affected / exposed	1 / 76 (1.32%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric arterial occlusion			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery thrombosis			
subjects affected / exposed	1 / 76 (1.32%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mesenteric artery embolism			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 76 (1.32%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug eruption			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	2 / 76 (2.63%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	7 / 7	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelocaliectasis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
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			
Flank pain			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Peritonitis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycobacterium avium complex infection			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
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 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Respiratory tract infection			

subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
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 / 76 (0.00%)	3 / 156 (1.92%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 76 (1.32%)	0 / 156 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			

subjects affected / exposed	1 / 76 (1.32%)	1 / 156 (0.64%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

<b>Non-serious adverse events</b>	Bosutinib	Asciminib	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 76 (94.74%)	130 / 156 (83.33%)	
Investigations			
Amylase increased			
subjects affected / exposed	4 / 76 (5.26%)	9 / 156 (5.77%)	
occurrences (all)	4	14	
Alanine aminotransferase increased			
subjects affected / exposed	23 / 76 (30.26%)	8 / 156 (5.13%)	
occurrences (all)	32	9	
Aspartate aminotransferase increased			
subjects affected / exposed	16 / 76 (21.05%)	9 / 156 (5.77%)	
occurrences (all)	22	9	
Neutrophil count decreased			
subjects affected / exposed	4 / 76 (5.26%)	8 / 156 (5.13%)	
occurrences (all)	7	14	
Lipase increased			
subjects affected / exposed	5 / 76 (6.58%)	8 / 156 (5.13%)	
occurrences (all)	7	18	
Blood creatinine increased			
subjects affected / exposed	6 / 76 (7.89%)	6 / 156 (3.85%)	
occurrences (all)	7	7	
Platelet count decreased			
subjects affected / exposed	5 / 76 (6.58%)	11 / 156 (7.05%)	
occurrences (all)	10	17	
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 76 (5.26%)	23 / 156 (14.74%)	
occurrences (all)	4	25	
Nervous system disorders			

Dizziness subjects affected / exposed occurrences (all)	3 / 76 (3.95%) 3	14 / 156 (8.97%) 16	
Headache subjects affected / exposed occurrences (all)	16 / 76 (21.05%) 19	31 / 156 (19.87%) 37	
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	6 / 76 (7.89%) 7	16 / 156 (10.26%) 16	
Thrombocytopenia subjects affected / exposed occurrences (all)	14 / 76 (18.42%) 42	36 / 156 (23.08%) 56	
Neutropenia subjects affected / exposed occurrences (all)	17 / 76 (22.37%) 61	30 / 156 (19.23%) 66	
General disorders and administration site conditions			
Influenza like illness subjects affected / exposed occurrences (all)	4 / 76 (5.26%) 4	3 / 156 (1.92%) 4	
Fatigue subjects affected / exposed occurrences (all)	8 / 76 (10.53%) 9	24 / 156 (15.38%) 28	
Asthenia subjects affected / exposed occurrences (all)	1 / 76 (1.32%) 1	14 / 156 (8.97%) 20	
Non-cardiac chest pain subjects affected / exposed occurrences (all)	1 / 76 (1.32%) 1	9 / 156 (5.77%) 13	
Oedema peripheral subjects affected / exposed occurrences (all)	3 / 76 (3.95%) 3	12 / 156 (7.69%) 15	
Pyrexia subjects affected / exposed occurrences (all)	7 / 76 (9.21%) 12	5 / 156 (3.21%) 5	
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	13 / 76 (17.11%)	14 / 156 (8.97%)	
occurrences (all)	14	15	
Abdominal pain upper			
subjects affected / exposed	5 / 76 (6.58%)	7 / 156 (4.49%)	
occurrences (all)	6	8	
Constipation			
subjects affected / exposed	4 / 76 (5.26%)	8 / 156 (5.13%)	
occurrences (all)	4	11	
Diarrhoea			
subjects affected / exposed	55 / 76 (72.37%)	20 / 156 (12.82%)	
occurrences (all)	84	21	
Dyspepsia			
subjects affected / exposed	3 / 76 (3.95%)	11 / 156 (7.05%)	
occurrences (all)	3	12	
Nausea			
subjects affected / exposed	36 / 76 (47.37%)	18 / 156 (11.54%)	
occurrences (all)	45	24	
Vomiting			
subjects affected / exposed	20 / 76 (26.32%)	12 / 156 (7.69%)	
occurrences (all)	28	18	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	2 / 76 (2.63%)	8 / 156 (5.13%)	
occurrences (all)	2	8	
Dyspnoea			
subjects affected / exposed	5 / 76 (6.58%)	8 / 156 (5.13%)	
occurrences (all)	5	8	
Cough			
subjects affected / exposed	6 / 76 (7.89%)	14 / 156 (8.97%)	
occurrences (all)	6	18	
Pleural effusion			
subjects affected / exposed	4 / 76 (5.26%)	2 / 156 (1.28%)	
occurrences (all)	8	2	
Skin and subcutaneous tissue disorders			

Pruritus subjects affected / exposed occurrences (all)	5 / 76 (6.58%) 8	8 / 156 (5.13%) 9	
Rash subjects affected / exposed occurrences (all)	18 / 76 (23.68%) 35	16 / 156 (10.26%) 17	
Rash maculo-papular subjects affected / exposed occurrences (all)	3 / 76 (3.95%) 3	8 / 156 (5.13%) 8	
Dry skin subjects affected / exposed occurrences (all)	6 / 76 (7.89%) 6	8 / 156 (5.13%) 8	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	1 / 76 (1.32%) 1	11 / 156 (7.05%) 12	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	2 / 76 (2.63%) 2	24 / 156 (15.38%) 35	
Back pain subjects affected / exposed occurrences (all)	4 / 76 (5.26%) 4	12 / 156 (7.69%) 14	
Muscle spasms subjects affected / exposed occurrences (all)	1 / 76 (1.32%) 2	8 / 156 (5.13%) 8	
Pain in extremity subjects affected / exposed occurrences (all)	5 / 76 (6.58%) 6	15 / 156 (9.62%) 18	
Myalgia subjects affected / exposed occurrences (all)	6 / 76 (7.89%) 6	10 / 156 (6.41%) 14	
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	3 / 76 (3.95%) 3	18 / 156 (11.54%) 21	



COVID-19			
subjects affected / exposed	5 / 76 (6.58%)	17 / 156 (10.90%)	
occurrences (all)	5	17	
Bronchitis			
subjects affected / exposed	4 / 76 (5.26%)	2 / 156 (1.28%)	
occurrences (all)	5	2	
Upper respiratory tract infection			
subjects affected / exposed	5 / 76 (6.58%)	13 / 156 (8.33%)	
occurrences (all)	8	16	
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	5 / 76 (6.58%)	2 / 156 (1.28%)	
occurrences (all)	6	2	
Decreased appetite			
subjects affected / exposed	6 / 76 (7.89%)	8 / 156 (5.13%)	
occurrences (all)	6	11	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 April 2017	The purpose of this amendment was to identify the exclusionary mutation correctly, as "V299L" in the protocol, which was inadvertently identified as "V229L" throughout the protocol. In addition, some inconsistencies were corrected.
13 July 2018	<p>The frequency of bone marrow aspirate (BMA) to perform cytogenetic analysis was decreased in accordance with treatment guidelines European LeukemiaNet (ELN) Guidelines and National Comprehensive Cancer Network (NCCN) guidelines. Initially BMAs were foreseen at screening, every 24 weeks thereafter and at EOT. With the protocol amendment BMA was no longer needed for participants that had achieved major molecular response (MMR) during study, however bone marrow aspirate (BMA) assessment was requested at end of treatment (EOT) for biomarker analysis.</p> <p>Based on the identification of pancreas as potential target tissues in the toxicity studies performed in rats, dogs and cynomolgus monkeys, the screening threshold for lipase was increased from <math>\leq</math> ULN to <math>\leq 1.5 \times</math> ULN (CTCAE v4.03 grade 1).</p> <p>The requirement of amylase screening was removed, because amylase was not considered as a specific marker for pancreatitis, as up to 60% of total serum amylase originates from non-pancreatic sources.</p>
14 December 2018	<p>For inclusion in the study, the threshold of <math>\geq 1\%</math> BCR::ABL1 was reduced to BCR::ABL1 ratio <math>&gt;0.1\%</math> IS for participants with intolerance to most recent TKI treatment.</p> <p>With this amendment, participants who had failed bosutinib were offered the possibility to continue in the study by receiving asciminib, if investigators considered that this treatment option was in the best interest of the participant.</p>
05 August 2020	Based on FDA request, requirement for male contraception was reintroduced in the study.

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> for complete trial results.

Notes: